FAO
FISHERIES
TECHNICAL
PAPER

442

ISSN 0429-9345

Application of risk assessment in the fish industry

Cover photographs:
Left: Fish processing plant in Latvia Right: Norwegian salmon farm. Courtesy of EUROFISH.

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, 2004

Reprinted 2005

ISBN 92-5-104951-3

PREPARATION OF THIS DOCUMENT

The Fishery Industries Division of the Food and Agriculture Organization of the United Nations (FAO) has produced this document to help those concerned with fish safety and quality to better understand about risk (microbiological and chemical) in the seafood industry and to be able to carry out work on risk assessment.

It aims at assisting those involved in any of the following:

- assessing the effectiveness of existing legislation;
- measuring the effect of a change in legislation on public health;
- measuring the effectiveness of a given safety assurance system;
- protecting an export market;
- assessing safety of imported seafoods;
- assessing equivalence between regulatory systems;
- identifying high risk products and pathogens;
- responding to outbreaks of food poisoning from a specific product and hazard;
- identifying where in the food chain control steps can best be applied.

The text works through examples of how risk analysis can be used for any of the above reasons. Dr John Sumner and Dr Tom Ross prepared this paper with assistance from Dr Lahsen Ababouch. The three have been associated with the work of FAO–World Health Organization (WHO) on microbiological risk assessment; the first two authors prepared risk assessments for the Australian seafood industry. Using their practical knowledge of the fish industry in Asia, the Pacific, South America, Africa and Europe, the authors attempted to demystify the concepts and provide a practical guide, written in simple language and using practical examples, to illustrate the exercises. The photographs were provided by Mr Masanami Izumi.

The authors wish you well in using this paper and the associated CD-ROM and welcome any comments and feedback you have so that we might make any necessary improvements.

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March 2004

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Sumner, J.; Ross, T.; Ababouch, L.
Application of risk assessment in the fish industry.
FAO Fisheries Technical Paper. No. 442. Rome, FAO. 2004. 78p.

ABSTRACT

In recent years, the concept of risk has become paramount in international food regulation. Industries are increasingly required to undertake product risk assessment, particularly in the export arena. This publication has been developed as a complete "How to" package on risk assessment for seafood technologists, regulators and health professionals. It is designed in five parts and takes the user from a basic knowledge to being able to conduct credible risk assessments:

1. The basics of risk assessment: definitions and language of the discipline
2. How to perform risk assessments: stepwise progression
3. How to use risk assessments: risk management, Hazard Analysis Critical Control Point (HACCP), risk profiling
4. Risk Ranger – how to use it
5. Examples of risk assessments: an interactive setting for the reader

This publication also includes the Resources Bank, a CD-ROM, which provides a large amount of additional information for the would-be risk assessor.

Distribution:
FAO Fisheries Department
FAO Regional and Subregional Fisheries Officers
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FOREWORD

The emerging world trading system is committed to transparent rules relating to food safety and quality based on the principle of equivalence and a scientific approach. This is particularly important for fish and fishery products, which today are more internationally traded than any other food product.

Whereas the concept of risk and food safety has been around for some time, it was the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) of the World Trade Organization (WTO), which came into effect in 1995 and set the stage for a risk approach to food control measures. It states that safety and quality rules should, where possible, reflect international standards, such as those of the Codex Alimentarius, but different national standards can be applied as long as they are scientifically based using risk assessment.

The risk approach to food safety embraces the fact that whereas carefully designed preventive systems, such as HACCP, can produce safe foods, complete safety cannot always be guaranteed at all times for all people. Therefore, communicating the risk associated with consumption of different foods becomes of prime importance.

The Codex Alimentarius Commission (CAC) has identified microbiological risk assessment for foods as a priority. Subsequently, the Codex Committee on Food Hygiene (CCFH) has identified 21 pathogen-product pairs for which it requires expert advice based on risk assessment. Of particular relevance for fishery products are risk assessments for *Vibrio* spp. in seafoods and *Listeria monocytogenes* in ready-to-eat foods – both of which are now near completion.

The Fishery Industries Division of FAO takes pride in helping the fish industry in developing countries to build capacity related to fish safety and quality with a focus on practical approaches. This publication explains the basics of microbiological and chemical risk assessment for seafoods to help "demystify" the area of risk assessment. It should primarily be seen as a working tool that allows for systematic ranking of the risks associated with different product categories – thus allowing for a more focused approach to producing safe aquatic foods. It has been widely used in Australia to profile entire segments of the food industry.

Grímur Valdimarsson
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CONTENTS

ACRONYMS

AIDS	acquired immune deficiency syndrome
AOAC	Association of Official Analytical Chemists
AQIS	Australian Quarantine and Inspection Service
CAC	Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
CFP	ciguatera fish poisoning
EU	European Union
EHEC	enterohaemorrhagic *Escherichia coli*
EPA	Environmental Protection Agency
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration (United States of America)
HACCP	Hazard Analysis Critical Control Point
HAV	Hepatitis A virus
HFP	histamine fish poisoning
HIV	human immunodeficiency virus
IFT	Institute of Food Technologists
JECFA	Joint Expert Committee on Food Additives
NACA	Network of Aquaculture Centres in Asia-Pacific
NAS	National Academy of Sciences (United States of America)
pTWI	provisional tolerable weekly intake
PCB	polychlorinated biphenyls
RfD	reference dose
SPS	Sanitary and Phytosanitary [Agreement]
SRSV	small round structured viruses
TBT	Technical Barriers toTrade [Agreement]
WHO	World Health Organization
WTO	World Trade Organization

Introduction

The use of risk assessment has gained steadily in importance and recognition as the scientifically-based approach for the development of food safety and quality standards. During recent years there has been increasing use of the word "risk" in connection with food safety, in general, and seafood safety in particular. There are statements such as *"regulations must be risk-based"*, *"a risk analysis must be done"* and *"we need to communicate the risk to all stakeholders"*.

Where has this emphasis on risk come from? Probably it is a logical extension of the Hazard Analysis Critical Control Point (HACCP) revolution that swept the industry in the 1980s and 1990s. HACCP Principle 1 states that a hazard analysis must be done. First those hazards that are likely to occur are identified, then an assessment is made of the severity of each hazard, followed by an evaluation of its likelihood to occur. These two factors (severity and likelihood) tell us about risk.

Another important drive towards risk assessment is the increase in international trade, which has raised new safety and quality challenges. Newer proactive quality and safety approaches have been developed to address the risk of cross-border transmission of infectious and hazardous agents and to deal with emerging food-borne diseases and quality problems. This has required the development of a new safety and quality regulatory framework that culminated with the entry into force, in 1995, of the Sanitary and Phytosanitary (SPS) and the Technical Barriers to Trade (TBT) Agreements of the World Trade Organization (WTO). Two provisions of these Agreements are of paramount importance to fish safety and quality:

- National SPS and quality requirements should reflect standards agreed on in the international standards setting bodies i.e. Codex Alimentarius for food quality and safety.
- Domestic standards, different from international ones, can be developed given they are scientifically based using risk assessment.

Risk assessment of microbiological hazards in foods has been identified as a priority area by the Codex Alimentarius Commission (CAC.) At its thirty-second session in 1999, the Codex Committee on Food Hygiene (CCFH) identified a list of 21 pathogen-commodity combinations that require expert risk assessment advice. In response, FAO and the World Health Organization (WHO) jointly launched a programme of work with the objective of providing expert advice on risk assessment of microbiological hazards in foods to their member countries and to the CAC. This involved establishing expert drafting groups to examine four priority pathogen:product pairings:

- *Listeria monocytogenes* in ready-to-eat food;
- *Salmonella* in eggs and broiler chickens;
- *Campylobacter* spp. in broiler chickens;
- *Vibrio* spp. in seafoods.

In view of all this, risk assessment is important throughout all aspects of the seafood industry – for companies, national governments and for international regulators. It does not matter where you operate in the seafood industry, risk assessment either already is an important part of your activity, or it soon will be. It can also be an expensive exercise, but in the end it should be worth the resources mobilized.

This paper is presented in five parts:

1. The basics of risk assessment
2. How to perform risk assessments

3. How to use risk assessments
4. Risk Ranger – how to use it
5. Examples of risk assessments

In addition, there is a CD-ROM, the Resource Bank, which provides selected back-up resources if an extensive library or online facilities are not available. It also includes a spreadsheet tool, Risk Ranger, to facilitate semi-quantitative risk assessments and risk profiles.

1. The basics of risk assessment

1.1 RISK AND RISK ANALYSIS IN PLAIN LANGUAGE

Risks from microbiological and chemical hazards are of serious concern to human health. As the discipline of risk analysis matures, it is developing its own tools and language, and this paper explains what those tools can do, in simple language. To begin, the definitions and terms used in risk analysis are set out in the CAC *Principles and guidelines for the conduct of microbiological risk assessment* (CAC/GL-30, 1999). The Codex words are in italics and some explanatory words are in normal type.

Risk

A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

Risk has two parts:

The likelihood that a hazard will affect us	The severity of its consequences if it does

Hazard

A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

There are two very useful books that give information on seafood hazards:

- *Assessment and management of seafood safety and other quality aspects* (FAO, 2004).
- *Fish and fisheries products hazards and controls guide* (FDA, 2001).

Risk analysis

A process consisting of three components:

- *risk assessment*
- *risk management*
- *risk communication*

A common question is "Which of the three elements do I do first?" In most cases, the risk managers identify the need for a risk assessment and select an assessment team. Ideally, they should also begin the risk communication process as early as possible so that all interested and affected groups know what is happening from the first day. Tactically, it is a mistake to keep people uninformed – even if they agree with the assessment they will be displeased to have been excluded from the process.

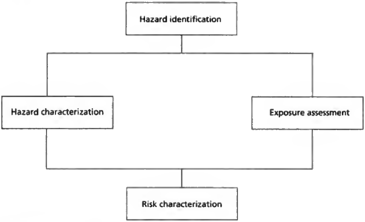
Risk assessment

A scientifically based process consisting of the following steps:

- *hazard identification*
- *hazard characterization*
- *exposure assessment*
- *risk characterization*

The aim of risk assessment is to estimate the level of illness that may be expected in our target population from a product or group of products.

The information flow for the four components in a risk assessment is shown below:



Hazard identification

The identification of biological, chemical and physical agents capable of causing adverse health effects and that may be present in a particular food or group of foods.

This is the first stage in risk assessment and is a screening process to make certain that the hazard really does exist in this particular product. For example, *Clostridium botulinum* is readily identified as a hazard in canned, smoked and vacuum-packed seafoods, but is unlikely to be a hazard for any other seafood product. So hazard identification is a primary screen that allows risk managers to eliminate product: pathogen pairs that are of no concern.

You will find material on hazard identification for all of the hazards associated with seafoods in the Resources Bank.

Hazard characterization

The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents that may be present in food. For the purpose of microbiological risk assessment the concerns relate to micro-organisms and/or their toxins.

There are two parts to hazard characterization:

- a description of the effects of the hazard (micro-organism or toxin);
- the dose-response relationship (if it exists).

Dose-response assessment

The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

For any particular individual, dose-response links the amount of the hazard you ingest (dose) with the chance of your becoming infected and the scale of the illness if you do. For example, most healthy individuals can consume large numbers of *Listeria monocytogenes* (maybe as many as 100 million cells) without becoming seriously ill. By contrast, in susceptible people (foetuses, the aged or individuals with impaired immune

systems) a much smaller dose (maybe as few as 10 000 cells) can cause serious illness and, in around 30 percent of cases, death. In the Resources Bank you will find a list of dose-responses for several micro-organisms and their toxins.

Exposure assessment

The qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures from other sources if relevant.

To carry out an exposure assessment you need data in two areas:

- number of servings of potentially dangerous food eaten;
- level of contamination with the micro-organism or toxin at the time of consumption.

To arrive at these types of data you will probably follow the micro-organism or toxin through the processing–food preparation chain and estimate changes that occur to the hazard throughout the chain.

Risk characterization

The process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

When you do the risk characterization, you integrate hazard identification, exposure assessment and hazard characterization to provide an estimate of the risk.

Risk estimate

Output of risk characterization

This may vary from a qualitative estimate (high, low, medium) to a quantitative estimate where you predict the number of people you expect will become ill from the particular product:hazard pairing. Alternately, your risk characterization may be semi-quantitative and you make a risk ranking that is a number in a specific range, 0–100, for example.

Risk management

The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant to the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

Risk managers have a difficult responsibility because they must take into account the views of various groups. Trying to find compromises between the views of scientists, industry, consumer groups, politicians and lawyers is almost impossible, but it is what risk managers are required todo.

Risk communication

The interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risk, risk-related factors and risk perceptions among risk assessors, risk managers, consumers, industry, the academic community and other interested groups, including the explanation of risk assessment findings and the basis of risk management decisions.

Communicating risk is a very difficult task because it involves the full range of stakeholders. A major problem is informing consumers that no food product is risk-free and, as a consequence, they must be prepared for X deaths and Y illnesses each year from this particular product. Risk communication includes changing perceptions of stakeholders so they all move towards some central positions that are not far removed from each other.

Quantitative risk assessment

A risk assessment that provides numerical expressions of risk and indication of the attendant uncertainties (WHO, 1995).

A typical quantitative risk assessment (QRA) was carried out by Lindqvist and Westöö (2000) for smoked fish in Sweden, where the predicted annual number of illnesses varied between 47 and 2 800 (mean 168) for consumers at most risk.

Qualitative risk assessment

A risk assessment based on data which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties, permits risk ranking or separation into descriptive categories of risk.

A typical qualitative risk assessment was done by Huss, Reilly and Ben Embarek (2000), who estimated the risk as high for consumption of molluscan shellfish, fish eaten raw, lightly preserved fish and mildly heat-treated fish. Low-risk products were chilled/frozen fish and crustaceans, semi-preserved fish and heat-processed (canned) fish. Dried and heavily salted fish were considered to have no risk.

Risk profile

A description of a food safety problem and its context developed for the purpose of identifying those elements of a hazard or risk that are relevant to risk management decisions. This approach has been used in Australia to profile entire food industries.

Risk profiling can be a way of quickly identifying those products within a particular sector that are of most concern. This is exactly what Huss, Reilly and Ben Embarek (2000) did in the previous example for the seafood industry, as a whole. If you did a risk profile of your industry you might find some difference in risk rating. For example, dried and heavily salted fish usually have no risk. But what if the rainy season led to mould formation and the moulds were able to produce aflatoxin? The risk rating will no longer be zero.

A recent report of a joint FAO/WHO (2002) consultation defines that the purpose of a risk profile is to enable a decision on what will be done next and whether resources should be allocated to a more detailed scientific assessment. A risk profile comprises a systematic collection of information needed to make a decision, and is the responsibility of the risk manager (although it may be commissioned out to appropriate parties).

Transparency

Characteristics of a process where the rationale, the logic of development, constraints, assumptions, value judgements, decisions, limitations and uncertainties of the expressed determination are fully and systematically stated, documented and accessible for review.

Whenever risk assessments are submitted for peer review or public comment, the reviewers often comment that there is a lack of transparency. This means that they were not able to find important data, or they could not understand a calculation, or the risk assessors did not fully explain their logic.

Uncertainty analysis

A method used to estimate the uncertainty associated with model inputs, assumptions and structure/form.

Risk assessments almost always contain a statement specifying that insufficient data were available in one or more areas and, as a result, a certain amount of caution should be attached to the estimate. Caution, as a result of lack of precise information, leads to uncertainty and you should always record the data gaps that lead to uncertainty. Later, if that knowledge becomes available, the level of uncertainty will be reduced so that the risk estimate becomes more accurate.

Principles and guidelines for risk assessment

In 1999 the CAC set out general principles and guidelines for the conduct of microbiological risk assessment (FAO/WHO, 2001). As we also consider non-microbiological hazards, these principles have been amended from the Codex Principles for Microbial Risk Assessment by omitting "microbiological" where appropriate. The principles state that:

1. Risk assessment should be soundly based upon science.
2. There should be functional separation between risk assessment and risk management.
3. Risk assessment should be conducted according to a structured approach that includes hazard identification, hazard characterization, exposure assessment and risk characterization.
4. A risk assessment should clearly state the purpose of the exercise, including the form of risk estimate that will be the output.
5. The conduct of a risk assessment should be transparent.
6. Any constraints that impact on the risk assessment, such as cost, resources or time, should be identified and their possible consequences described.
7. The risk estimate should contain a description of uncertainty and where the uncertainty arose during the risk assessment process.
8. Data should be such that uncertainty in the risk estimate can be determined; data and data collection systems should, as far as possible, be of sufficient quality and precision that uncertainty in the risk estimate is minimized.
9. A microbiological risk assessment should explicitly consider the dynamics of microbiological growth, survival, and death in foods and the complexity of the interaction (including sequelae) between human and agent following consumption, as well as the potential for further spread.
10. Wherever possible, risk estimates should be reassessed over time by comparison with independent human illness data.
11. A risk assessment may need re-evaluation as new relevant information becomes available.

1.2 TYPES OF RISK ASSESSMENT

There are several types of risk assessment that fall under three broad categories:

- qualitative risk assessment;
- semi-quantitative risk assessment;
- quantitative risk assessment.

All three categories provide useful information and your choice of assessment will depend on the speed and complexity you require from your assessment.

1.1.1 Qualitative risk assessments

These are the simplest and quickest to do, but they can be rather subjective, which reduces their value. Every HACCP plan contains simple qualitative risk assessments in the HACCP worksheet.

For every hazard, an estimate of risk is made by inserting high, medium or low in answer to questions on the severity of the hazard and the likelihood of it occurring. A basic problem is that the three descriptors (high, medium, low) are often inadequate. For example, suppose the process step is retorting in fish canning and the hazard is *Clostridium botulinum*. Almost everyone will describe the severity of the hazard as high. But how likely is the hazard to occur? Most people will put low because billions

Type 1: Hazard control worksheet

Process step	Hazard	What can go wrong	Risk		Hazard control
			Severity of hazard	Likelihood of hazard occurring	
	BIOLOGICAL				
	CHEMICAL				
	PHYSICAL				

of cans of fish are manufactured each year with no sign of the hazard. High severity and low likelihood – how would you link these to estimate risk?

Another type of qualitative risk assessment is shown below, in which the risk estimate is a risk ranking – high, low and medium.

Type 2: Qualitative risk ranking

Hazard	Product	Severity of hazard	Likelihood of occurrence	Exposure in diet	Linkage with epidemiology	Risk ranking

This assessment is based on factors which are linked with exposure assessment (likelihood of occurrence and exposure in the diet) plus one which is linked with hazard characterization (severity of hazard). If the hazard:product pairing has some linkage with epidemiology (it has caused food poisonings), this serves to remind you that there is some probability that it will happen again.

So, in Type 2 (above) we can make some assessment of exposure from our responses to likelihood of occurrence and exposure in the diet. Suppose we are considering ciguatera in two different populations, e.g. people in a Pacific island atoll community and the population of the United Kingdom. For the Pacific you would probably say the likelihood of occurrence of ciguatera is high. For the United Kingdom, you would probably say likelihood of occurrence is very low. There are strong links with epidemiology in atoll communities where the hazard is more or less accepted as an unavoidable fact of life; in contrast, ciguatera only rarely occurs in the United Kingdom from imported reef fish.

When all the information is brought together into a risk ranking you probably have a high or very high ranking for the Pacific and a low or very low ranking for the United Kingdom. The ranking will have value if you need a clear-cut answer in a relatively short time. To get the answer you will need to research the hazard and discover that it may have a cumulative effect but that it is rarely fatal. You will also look into epidemiology of the two target consumer groups – a few thousand atoll residents and 60 million United Kingdom residents. If you can find a recent review of ciguatera, especially one that is written in a risk assessment context, you could complete your research in a short time.

Another qualitative scheme for categorizing risk from seafoods has been developed by Huss, Reilly and Ben Embarek (2000) who ascribe pluses to hazard, then rank risks as "high" (four or more pluses) or "low" (less than four pluses). The scheme takes into account epidemiology (bad safety record) and then focuses on the process, searching for a critical control point (CCP) for each hazard and assessing possibilities for growth and death of microbial hazards.

Type 3: Qualitative risk assessment based on the process

Risk criteria	Raw molluscan shellfish	Canned fish	Dried fish
Bad safety record	+	+	-
No CCP for the hazard	+	-	-
Possibility of contamination or recontamination	+	+	-
Abusive handling possible	+	-	-
Growth of pathogens can occur	+	-	-
No terminal heating step	+	+	+
Risk category	High	Low	No risk

Source: after Huss, Reilly and Ben Embarek (2000).

So, as shown in Type 3, molluscan shellfish, fish eaten raw, lightly-preserved fish and mildly heat-treated fish are considered "high" risk, while chilled/frozen fish and crustaceans, semi-preserved fish and heat-processed (canned) fish are considered "low" risk; dried and heavily salted fish are considered to have no risk.

1.1.2 Semi-quantitative risk assessment

In qualitative risk qssessment, we estimated risk according to subjective terms such as high, low or medium. In semi-quantitative risk assessment we obtain a numerical risk estimate based on a mixture of qualitative and quantitative data. To do this type of assessment you need much of the data that will be used in a full quantitative risk assessment. There is a great deal of work involved, but not as much as for a full quantitative risk assessment.

Ross and Sumner (2002) developed a simple spreadsheet tool to describe the risk that emerges from pathogens in products manufactured by typical processes (canning, chilling, cooking, etc). Table 1 lists risk criteria needed for a semi-quantitative risk assessment. These are simple questions and they can be answered qualitatively in terms such as "high" and "low". But the researchers found it possible to insert a quantitative basis to the answers. The tool is in Microsoft® Excel spreadsheet software and uses standard mathematical and logical functions. You can mouse-click your qualitative inputs, and the software will automatically convert them into quantities for calculations.

You must generate some data in order to answer the eleven questions in Table 1. To help you make your inputs as objective as possible, and to maintain transparency of the model, descriptions of the subjective descriptors are provided and many of

TABLE 1
Typical risk criteria in a semi-quantitative risk assessment

Risk criteria	Input
Dose and severity	
1. Hazard severity	
2. Susceptibility	
Probability of exposure	
3. Frequency of consumption	
4. Proportion consuming	
5. Size of population	
Probability of infective dose	
6. Probability of contamination	
7. Effect of process	
8. Possibility of recontamination	
9 Post-process control	
10. Increase to infective dose	
11. Effect of treatment before eating	

the weighting factors are specified in the lists of descriptors. Alternatively, where the options provided do not accurately reflect the situation being modelled, you can enter a numerical value that is appropriate.

The details behind the model can be read from the publication of Ross and Sumner (2002). Section 4 gives details about the tool, called Risk Ranger, and you can use it to work through some examples. The most robust risk estimates from Risk Ranger are a risk ranking (score from 0 to 100) and the number of illnesses per annum. This tool was used to provide a risk profile for the Australian seafood industry; later we will show you how its estimates were used to focus on those products and pathogens which required most attention from the industry.

1.1.3 Quantitative risk assessment

Quantitative risk assessments (QRAs) are done for specific purposes and provide numerical risk estimates to answer questions that were posed by the risk managers who originally commissioned the assessment. In the seafood area there have been three QRAs:

- *Listeria monocytogenes* in smoked fish in Sweden (Lindqvist and Westöö, 2000);
- *Vibrio parahaemolyticus* in oysters in the United States (FDA, 2000);
- *Listeria monocytogenes* in a range of seafoods in the United States (FDA, 2001).

The United States risk assessments were very large, taking more than one year to prepare and then moving to a 1–2 year review period of public comment. The *L. monocytogenes* risk assessment involved more than 30 people arranged in six teams, each of which was assigned specific tasks; more than 50 additional participants were acknowledged for their assistance. It must be stressed that this QRA involved a range of foods, not just seafoods, but the QRA of *V. parahaemolyticus* in oysters also involved more than 20 people who received information from scientists at more than 20 institutions in the United States and internationally. The Swedish QRA had two authors and acknowledged the help of two collaborators.

The resources invested in the two United States risk assessments were undoubtedly in response to large outbreaks of food poisoning in that country. In 1997 and 1998 there were two incidents involving *V. parahaemolyticus* in oysters involving more than 700 cases of illness, which led to the commissioning of the QRA. Also in the late 1990s there were two listeriosis incidents in the United States involving hot dogs and delicatessen meats in which more than 130 were seriously ill and 28 died.

Setting objectives – statement of purpose

In a QRA, it is vital to define what you want the work to achieve, and to do this right at the beginning. This is called a Statement of Purpose. In the United States, the risk managers stipulated that, for *V. parahaemolyticus* in oysters, the risk assessors:

1. produce a mathematical model of the risk of illness incurred by consumers of raw oysters containing pathogenic *V. parahaemolyticus*;
2. provide the regulators with information to assist with reviewing current regulations to ensure that they protect public health by evaluating:
   - current criteria for closing and reopening shellfish waters to harvesting;
   - preventive and intervention measures for controlling *V. parahaemolyticus* in oysters;
   - current guidance on allowing up to 10 000 cfu/g of *V. parahaemolyticus* in oyster meat.

For *L. monocytogenes*, the Statement of Purpose was to examine available scientific data systematically in order to estimate the relative risks of serious illness and death that might be associated with consumption of different types of ready-to-eat foods that might be contaminated with *L. monocytogenes*. The work produced mathematical models to predict contamination at the retail level and in the home, and different

consumer groups were included in the assessment. The result was predicted rates of listeriosis from various foods for various at-risk groups.

In Sweden, Lindqvist and Westöö (2000) set the objective to develop a QRA for estimating the exposure and risk of acquiring listeriosis from consumption of packaged smoked or gravad salmon and rainbow trout.

Modelling the process

In the seafood industry, the process is usually stretched out from harvesting, storing prior to processing, processing in the seafood plant, storing/distributing, retailing and consumption. Whatever the seafood product you are considering, the hazard may change throughout the process, either in prevalence or in concentration. We need to chart these changes often by making a process flow diagram and then mathematically measure or estimate changes in the hazard at each stage. In risk assessment this is called "modelling". Usually modellers try to make a "farm-to-fork" model that takes in changes to the hazard all along the harvest–process–consumption route. This part of the risk assessment is best done by people who understand the industrial process and combined with microbiologists who understand the hazard and how it reacts to changes, particularly to changes in temperature and time.

When the model of the system has been set, data must be gathered (exposure assessment). Ideally, there would be time to carry out experiments that give you exactly the data you need but, almost always, there are not sufficient resources or time to do this. So you need to investigate all sources of existing data and try to incorporate them into the model. This is where the modeller on your team takes the data and constructs mathematical relationships that describe changes in the hazard throughout the process. The modeller will encounter a number of problems, the most common being variability and uncertainty.

Variability

This occurs because of the diversity in any population, and it cannot be reduced, no matter how much the property is studied. To illustrate, let us use height as an example. In any population there is variability in height. We could do a survey by measuring how tall people are, and we would find most adults are 160–175 cm tall but that some are 220 cm while others are 120 cm. This is an example of variability within a population.

Uncertainty

This is due to our (the risk assessor's) lack of knowledge about a parameter and our inability to measure it. Uncertainty can be reduced if we study the characteristic. Using the same example of peoples' height, we could do a national survey and measure everyone. Then there would be no uncertainty.

Distributions

The risk is never fixed – it varies according to a range of parameters. For example, take the risk of dying in an air crash. For the vast majority of people on this earth the risk is zero because they never fly but, among those many millions who do fly, the risk varies according to how often they fly (likelihood), the airline (some have more crashes than others), the weather conditions (many crashes occur in bad weather) and the country (some have better systems than others). So estimating the risk is difficult because there is a distribution of risk from very low, through average to very high. Often the best estimate of distribution is minimum, most likely (average) and maximum value. For example, we might say the bacterial levels of shrimp landed aboard a trawler ranged from 10/g to 10 000/g, with the most likely count being 100/g.

Type of model

Modellers generally use simulation or stochastic modelling in which data are inserted into a spreadsheet. Computer software is then used to analyse the data. Each analysis is called an iteration where a value is selected from the distribution describing each variable range, more or less at random, but according to the probability distribution of that variable (more likely values are run more frequently than minimum or maximum values). A large number of iterations is run (10 000 is a popular number) and collated; the technique is called Monte Carlo simulation. The result is a distribution frequency of possible outcomes, which forms the basis of the risk estimate.

Risk estimate

The way you estimate the risk in a QRA is usually set by the statement of purpose. For example, Lindqvist and Westöö (2000) estimated the risk of acquiring listeriosis, and so risk estimates included the number of cases per annum and risk of becoming ill on a per serving basis. The researchers used two models and so had two estimates for each output. In the United States, the relative risk of acquiring listeriosis from a range of foods was the estimate, with pâtés, smoked seafoods, soft cheeses and delicatessen meats being the four most likely to cause the illness. For *V. parahaemolyticus* in oysters the single most important factor related to risk of illness was temperature – of air and water (seasonality). The model predicted nationwide illnesses of 4 750 per annum with a range of 1 000 to 16 000 cases. The model also indicated that risk of illness was reduced if product temperature could be lowered soon after harvest.

Reality check

When you have the risk estimates it is a good idea to do a reality check to see that the model is not predicting something that will seem absurd. For example, suppose you are estimating the number of cases of listeriosis caused by consumption of smoked fish and the model predicts the most likely scenario of 1 million cases each year. If your country statistics on illness and death state that there are 1 000 such cases each year, you know there is something wrong either with the model or with the inputs. You have more work to do!

Sensitivity (importance) analysis

As the software grinds through the iterations it also keeps a record of which factors have the biggest effect on risk estimate. This allows you to do sensitivity or importance analysis to identify those factors most influencing risk – either reducing or increasing it. This analysis then points risk managers to those areas where process control can be increased.

Summary

Risk assessments range in complexity from qualitative, through semi-quantitative to quantitative. As assessments become more complex, they also become more expensive and take longer to complete. So before you begin a risk assessment be sure you know exactly what you want or you may end up using resources unnecessarily.

2. How to perform risk assessments

To carry out risk assessments you need resources – people, information and data handling. Even modest assessments will cost in the tens of thousands of dollars and some of the very large QRAs probably exceed the million dollar mark. So before you make an investment in risk assessment you should have at least one good reason for doing it. Of course, the need may already have been specified for you, for example, by regulators in a country to which you export. Suppose all the major seafood importing blocs (European Union, United States, Japan) decide that they require risk estimates for all products they import – then every exporting country would have to respond to that requirement.

2.1 PROCESS INITIATION

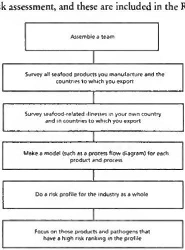
The first task is called process initiation – getting started on responding to your customers' requirements. One strategy is to proceed in the following manner.

Stage 1: Assemble a team

As for HACCP planning, you need a team that covers a range of disciplines:

- a seafood technologist with knowledge of processes and products;
- a food microbiologist who knows about microbial ecology;
- a statistician to assemble and handle data;
- a manager to direct the work

As the manager, it is your task to find the specialists needed to undertake the risk assessment work on behalf of your country. In larger countries with a history of seafood exports, this will not be a great problem. In smaller countries, however, you may need help. Together with WHO, FAO has prepared a number of texts that take you to advanced levels in risk assessment, and these are included in the Resources Bank.



Stage 2: Survey the industry

Make a survey of all the seafood products you manufacture and the countries to which you export. This is a straightforward task since every nation keeps a record of its seafood production volumes and species.

Stage 3: Survey seafood-related illness

Do a preliminary study of seafood-related illnesses in your own country as well as in countries to which you export. This will set the scene for doing a risk profiling exercise.

If your Health Department keeps records of food poisoning incidents, that is a good place to start your survey. You can make a list of seafood incidents, linking products with hazards (micro-organisms and toxins) and include these hazard:product pairs in the risk profile. In many countries, however, resources are so scarce that keeping statistics is not a high priority so you should spend some time searching and talking to people who would be likely to know of any illnesses caused by seafood consumption. This is purely anecdotal evidence but has some value – therefore make notes of your conversations.

The next stage is to look for statistics from customer countries. If you have Internet access, there are a number of Web sites, some of which are listed below, where information on food poisonings are included (Table 2).

TABLE 2
Sources of information on seafood illness and recalls of seafoods

Country	Organization	Web site
European Union	Eurosurveillance Weekly	http://www.eurosurv.org
USA	Centre for Science in the Public Interest	http://www.cspinet.org
USA	Morbidity and Mortality Weekly	http://www.cdc.gov/mmwr
UK	Public Health Laboratory Service (PHLS)	http://www.phls.nhs.uk
Australia	Communicable Diseases Intelligence	http://www.health.gov.au
Australia	Food Standards Australia and NZ	http://www.anzfa.gov.au
International	Food Safety Network	http://www.foodsafetynetwork.ca

Once you have gathered data, assemble them into a summary table. A collection of outbreaks of seafood-related illness in the United States and Australia over the period 1990–2000 is an example of the hazards and products involved in those countries (Table 3).

The data in Table 3 are valuable because they:

- identify the main seafood hazards;
- provide background on what has caused problems in importing countries.

If you look a little more carefully at the data, you can make a list of hazards and products that will shape your risk profiling exercise (Table 4).

You now have a list that can form the basis of your risk profile. There may be other perceived issues that need to be added to the list, for example mercury in species such as swordfish, and sulphite or chloramphenicol in shrimp. Some countries perceive these as food safety issues and they also become trade issues, so they are important, and you may wish to assemble some information on them.

TABLE 3
Seafood related illnesses in the United States and Australia (1990–2000)

	USA		Australia	
Category	Cases	Outbreaks	Cases	Outbreaks
Ciguatera	328	75	616	10
Histamine	680	103	28	10
Viruses	1 573	13	1 737	3
Bacterial pathogens	1 246	35	159	6
Biotoxins	125	9	102	3
Total	3 952	235	2 642	32

TABLE 4
Hazards and products that should be included in the risk profile

Hazard	Product
Chemical hazards	
Ciguatera	Reef fish
Mercury	Predaceous fish
Sulphite	Shrimp
Biotoxins	Bivalve molluscs
Biological hazards	
Viruses	Bivalve molluscs
Listeria monocytogenes	Smoked seafoods
Salmonella	Cooked shrimp
Vibrio parahaemolyticus	Shellfish eaten raw
Staphylococcus aureus	Cooked seafoods
Clostridium botulinum	Canned, vacuum-packed seafoods
Histamine	Scombroid fish
Parasites	Raw fish

Further reading on seafood statistics
If you want to read in more depth about statistics on seafood-borne diseases there is a section in *Assessment and management of seafood safety and other quality aspects,* which you will find in the Resources Bank.

Stage 4: Do a risk profile

If you do a risk profile of the industry as a whole this will give you a focus on products and pathogens of most concern. For the purpose of this document, risk profiling is defined as "*a description of a food safety problem and its context developed for the purpose of identifying those elements of a hazard or risk that are relevant to risk management decisions*".

This phase of the work entails gathering data in three areas:

- hazard identification
- hazard characterization
- exposure assessment

Once this is done you will know which pathogen:product pairings should be investigated as a matter of priority.

2.2 HAZARD IDENTIFICATION

For each of the hazard:product pairings you identified in Table 3 you now look for:

- links with confirmed food-borne illnesses both in your country and in importing countries; search the published literature and any national health statistics;
- international food-borne disease outbreaks;
- recalls monitored by food authorities in importing countries.

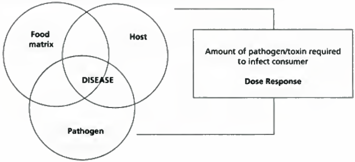
When you put all this information together you will have some idea of the food safety relevance of the hazard:product pairing.

At this stage you will be in a position to verify whether a particular hazard: product pairing is sufficiently important to remain in the risk profile. If it has not caused any problems, then you can use your resources more accurately on other pairings. For example, you may decide not to include parasitic worms in your risk profile because all finfish you export are frozen fillets and freezing kills the parasites. In other words, there are critical control points (freezing and frozen storage) that eliminate the hazard and, with it, the risk.

The Resources Bank includes hazard identifications of all the hazard:product pairings included in Table 3. This will get you started on your risk profiles but you should update the information by searching the sources recommended above (Table 2).

2.3 HAZARD CHARACTERIZATION

Hazard characterization is composed of inter-relationships, which are summarized in this simple diagram.



The three main areas for consideration – the pathogen/toxin, the host and the food matrix – all combine to make hazard characterization a very complex part of risk assessment. The simplest way of thinking about hazard characterization is to consider what happens whenever there is large-scale food poisoning. In general, only a proportion of consumers become ill, of whom a much smaller proportion may die. Why does not everyone become ill and why do not all those affected die? The reasons are many and complex but let us identify some of them by looking at a large outbreak of listeriosis from Mexican cheese. The main factors are summarized below.

Case history: Listeriosis in California in 1985 from consumption of Mexican cheese

Total of 142 cases of human listeriosis in California
Pregnant women: 93 cases (65.5 percent)
Death occurred in 30/93 cases (32.2 percent) – all were foetuses or newly-born babies
Non-pregnant adults were 49 cases (34.5 percent)
Immunocompromized: 38 cases (3 had cancer, 12 were taking steroids and 23 had chronic illness such as diabetes, renal disease, heart failure or cirrhosis)
Elderly: 5 cases (>65 years)
AIDS: 3 cases
Post-partum (just given birth): 2 cases
Full details are available in Linnan et al. *(1988).*

(i) The host

The illnesses occurred over the first eight months of 1985, during which time it is fair to assume that there were many thousands, if not millions, of servings of Mexican cheese eaten from the implicated factory. Because we do not know how many servings there were, we have no idea of the attack rate. We do know that 142 women were admitted to hospital with listeriosis, and these may have been a very small proportion of those who ate contaminated cheese. All of the 142 individuals were vulnerable:

- pregnant
- foetuses
- Newly-born
- immunocompromised
- elderly

In addition to the 142 cases of listeriosis, there may have been cases of gastro-enteritis due to the contaminated cheese, which did not show up in the health statistics

for California because the symptoms were not severe enough to warrant a visit to the doctor.

(ii) The pathogen

The pathogen, *Listeria monocytogenes*, has several properties that allow it to infect particular groups:

- It can cross the placenta and infect the foetus.
- The number of cells needed to cause listeriosis is probably much lower for vulnerable groups.

(iii) The food matrix

There are several aspects of the microbial ecology of *L. monocytogenes* in Mexican cheese that give it a competitive advantage:

- tolerance to the salt levels in cheese while competing bacteria are inhibited by salt;
- ability to grow in the refrigerator;
- possible protection within curd particles or fat through the stomach of the consumer.

The above case history defines the three broad areas of information you need when you think about hazard characterization. Let us consider them in enough detail so you will be able to do your own hazard characterization.

2.3.1 Consumers (hosts)

When we think about consumers (hosts) we need some background on why some people become infected more readily than others. Then it is necessary to know how many consumers fall into at-risk groups. The Resources Bank contains a background publication, *Natural defences to illness*, which gives information on how people cope with the invasion of pathogens.

For various reasons, all individuals lose immunity either progressively as they age, or catastrophically if they undergo chemo- or radiotherapy or if they acquire diseases that impair the immune system. But how many are there in society who are likely to be more vulnerable to infection? To calculate this proportion you need access to national statistics but, if these do not exist, you can use 20 percent as a reasonable indication. Table 6 shows that 20–25 percent of Australians fall into the vulnerable category, and this level seems similar for other western countries. The relevant subcategories are given below.

- *Ageing*

You can look at national statistics to estimate the number of elderly and aged people in the community. Sort your data into a summary similar to that shown in Table 5; data from Australian statistics are given as an example of how age categories break down across a society.

Antibody levels are highest in childhood. By age 55, levels are reduced on average by 50 percent, and by 90 years of age only 25 percent of the original antibody level remains. The aged also have a reduced neutrophil function, which reduces intracellular antimicrobial activity. The loss of immunity and antimicrobial activity in the "very old" segment is of particular concern because it is a segment that is increasing in developed countries, which incidentally also represents the major importers of seafood products.

TABLE 5

Estimated numbers of elderly and aged people in the population

Age group	No. of males (%)	No. of females (%)
55–64	4.2	4.2
65–74	2.3	2.6
75–84	1.6	2.3
85 and over	0.3	0.8
Total	8.4	9.9

• ***Acquired immune deficiency syndrome***
Those infected with human immunodeficiency virus (HIV) are at increased risk of gastro-enteric infections, in general, and of *Salmonella* infection, in particular.

• ***Cancer***
Each year new cases of cancer are diagnosed that require therapy. Cancers most likely to increase an individual's susceptibility to food-borne disease are lung, bowel, breast, lymphoma, leukemia and renal. It is difficult to estimate those undergoing cancer treatments but, if the median treatment time is five years, it is likely that large numbers within the population are affected.

• ***Diabetes***
Consumption and lifestyle patterns in developed countries have seen a rise in the number of sufferers of this disease, of whom around 10 percent are insulin-dependent. Non-insulin-dependent diabetes is more common in those older individuals who are overweight and sedentary. It is estimated that a similar number are undiagnosed, asymptomatic diabetics. Diabetes is particularly common among indigenous and Pacific island groups, with prevalence rates for the former approaching 100 cases/1 000 people.

• ***Pregnancy***
There are two phases of pregnancy during which mother or foetus are at greater risk. In the first trimester, foetuses are at risk from the effects of heavy metals. In the third trimester both mother and foetus are susceptible to *Listeria monocytogenes*.

• ***Very young***
Children younger than five years are considered to have a greater risk of food-borne illnesses. The prevalence of salmonellosis among children less than six months old is probably due to low gastric acidity, immature immune response and low protective effect from residential gut microflora (D'Aoust, 1994).

• ***Hypochlorhydria***
In many western countries people use preparations to reduce stomach acidity. It is difficult to determine the proportion of individuals who take an acid-lowering agent but it is likely to be significant, perhaps as high as 1–5 percent.

As an example, Table 6 summarizes the at-risk segments in the Australian population. It is likely that 20–25 percent of Australians have impaired defence to microbial pathogens with some, the very old, having multiple impairment factors.

The linkage between a predisposing condition and infection from food-borne micro-organisms has been well-documented. In an outbreak of *Vibrio vulnificus* in Los Angeles in 1996, three people died after consuming oysters; a 38-year old man was a heavy consumer of alcohol and also an insulin-dependent diabetic; a 46-year old man was an alcoholic and had contracted jaundice; a 51-year old woman had had breast cancer and chronic Hepatitis C (Mascola *et al.*, 1996).

In Australia, four cases of septicaemia from *V. vulnificus* related to oyster consumption involved people aged between 53 and 74, all with chronic liver disease; two people died (McAnulty, 1990).

In summary, when considering the risk of infection, both the general population and those predisposed to the hazard must be considered.

TABLE 6
Susceptible populations and proportions in Australian society in 2000

Population	Percentage
Pregnancies	1.25
Neonates	1.35
Children 1–5	7.02
Elderly >60	16.01
Elderly >55	20.50
Diabetes (insulin-dependent)	0.36
Diabetes (non-insulin-dependent)	2.50
Cancer patients	2.10
AIDS patients	0.1

2.3.2 Dose-response

Dose-response is a measure of how much disease agent is required to cause illness. For example, how many salmonella cells in a meal of cooked shrimp are needed to give you salmonellosis? How many Hepatitis A virus (HAV) particles could you eat in a meal of raw oysters without contracting hepatitis? How much ciguatoxin must there be in a reef fish before you get ciguatera poisoning? In the first place, it all begins with you. If you are in a susceptible group, the number of micro-organisms needed to make you ill will be much lower than if you are not susceptible.

Then, the ability of the specific micro-organism becomes important – its virulence or pathogenicity. We have been able to gain some information on how many micro-organisms are required to cause illness by conducting a range of studies:

- ***Volunteer feeding studies***

This is a straightforward way of finding out how many micro-organisms are required to cause illness. In early studies, men serving prison sentences were fed meals containing different levels of *Salmonella*, and at least 100 000 living cells were needed before illness occurred (Bryan, 1979). It is doubtful whether volunteer feeding studies will ever be done in future because of changes in the way society feels about such a study. So alternate methods need to be found.

- ***Epidemic data***

Whenever an outbreak of food poisoning occurs, leftover food is tested, if possible, to find out the causative organism and its population. The results of such tests sometimes cause a re-think on how many organisms are needed to produce illness. For example, early findings that a person needs to eat >100 000 cells of *Salmonella* to become ill have been shown to be not always true because, in a number of outbreaks, only a few caused infection (Table 7).

The food matrix, especially its fat content, is important and all the foods in Table 7 have high fat contents, which may protect the salmonellas from gastric juices.

In other outbreaks, the numbers needed for illness have appeared much higher than previously thought. For example, in Australia, three people became ill after eating smoked mussels. The level of *L. monocytogenes* in the mussels was >10 million/g, suggesting that more than 100 million listerias were consumed in each meal. Although all three people were ill (and one was 83 years old) the illness was confined to gastro-enteritis and did not progress to listeriosis.

TABLE 7
Examples of salmonelloses produced by serovars at low dosage

Vehicle	Serovar	Infectious dose
Chocolate	*S. eastbourne*	100
Chocolate	*S. napoli*	10–100
Chocolate	*S. typhimurium*	<10
Cheese	*S. heidelberg*	100
Cheese	*S. typhimurium*	1–10
Hamburger	*S. newport*	10–100

Source: after D'Aoust, 1994.

- ***Surveillance statistics***

Many countries keep statistics to link types of pathogens with numbers of illnesses. In many western countries these statistics show that *Campylobacter* and *Salmonella* cause the vast majority of illnesses reported to doctors. But not all campylobacters and salmonellas are equally capable of causing illness. For example, in Australia, the major *Salmonella* on poultry is *S. Sophia* but, although it is present on the majority of chicken carcases, it causes only a small proportion of illnesses, suggesting its dose-response is different from that of other salmonellas.

- ***Animal studies***

Laboratory animals have long been used instead of humans to try and determine how much disease-causing agent is needed to cause symptoms. These animals range from

mice, which are cheap to raise and feed, to primates and pigs, which are obviously more expensive. There are disadvantages in using laboratory animals, both because their response may be different from that of humans, and also because, in many countries, there is ethical opposition to making animals suffer. Nonetheless, mouse injection is important in studying the toxin of *Clostridium botulinum*, one of the most dangerous organisms in seafoods.

• In-vitro *studies*
It is now possible to maintain cell lines in culture and to test toxins and micro-organisms under controlled conditions. The major limitation is that it is difficult to relate the findings to human dose-response.

So what is known about the dose-response of different disease-causing agents associated with seafoods? Table 8 summarizes the levels required to cause illness and are an indication of the relative toxicity of seafood toxins ranging from the very high toxicity of botulinum toxin to the relatively low toxicity of histamine. For micro-organisms, there is great disparity between levels required to infect susceptible versus non-susceptible individuals.

TABLE 8
Ranges of agents associated with seafoods needed to cause disease

Agent	Susceptible groups	Non-susceptible groups
Toxins	Based on 50-kg person	
Ciguatera	approx 50/ng	approx 1 ng/kg body weight
Histamine	approx 50/mg	approx 1 mg/kg body weight
Paralytic shellfish poison	150–1 500 µg	150–1 500 µg
C. botulinum toxin	0.1–1.0 µg	0.1–1.0 µg
Micro-organisms		
Salmonella	10–100 cells	100 000 cells
Vibrio parahaemolyticus	>10 000 cells	>10 000 cells
Listeria monocytogenes	1 000–10 000 cells	>1 000 000 cells
Hepatitis A virus	1–10 particles	10–100 particles

The Resources Bank includes information on hazard characterization for each of the above agents, including:

- virulence and infectivity for various consumer groups (vulnerable and non-vulnerable);
- illness caused (time of onset, duration, symptoms);
- sequelae (ability to cause further conditions such as arthritis);
- effect of food matrix (composition, processing, meal preparation, etc.) on the agent.

Dose-response models

"Modelling" is an important part of risk assessment studies, and risk modellers have become an integral part of risk assessment work. Risk modellers think differently from microbiologists and food technologists. The latter worry if they do not have reliable data. Modellers, on the other hand, say "*No problem – we will model it*", which ends up worrying the microbiologists even more! However, modellers are indispensable if you are going to do quantitative risk assessments.

There are several models surrounding dose-response described in *FAO/WHO guidelines on hazard characterization for pathogens in food and water*, which is supplied in the Resources Bank.

2.4 EXPOSURE ASSESSMENT

For any component in our diet, exposure to a disease-causing agent (toxin or micro-organism) in that component depends on three factors:

- the level of the agent in the meal;
- the amount we eat (serving size);
- the frequency with which people consume that component.

Let us take an example – ciguatera in reef fish. Suppose you live on a Pacific atoll. Seafood plays a large part in your diet. You probably eat it every day, including species such as Spanish mackerel, which are caught off the reef, and you may consume up to 250 g of finfish at one sitting. Compare that exposure with a consumer in a European city, where seafood is eaten once a week, serving size around 100 g, with reef fish eaten once a year. Obviously the exposure to ciguatera in the two communities is very different. A consumer on an atoll may consume 50 kg of reef fish each year, compared with 100 g for the European city dweller.

The above comparison shows a 500-times difference in potential exposure, based only on mass consumed. In fact, assessing exposure is rather more complicated because there are usually a large number of other factors to consider such as:

- frequency of contamination (prevalence) with toxin or pathogen;
- changes in level of contamination through the marketing chain;
- seasonal effects;
- consumption patterns;
- susceptibility of consumer;
- preparation effects.

In Section 5, Examples of risk assessments, there are examples of how to do the work needed under exposure assessment. This is the part of a risk assessment where you need to do much investigative work. The better the exposure assessment, the more valid will be your risk estimate. Availability of local data is very important for exposure assessment.

2.5 RISK CHARACTERIZATION

In risk characterization, all previous information from hazard identification, exposure assessment and hazard characterization are brought together to give a picture of the risk. The picture is an estimate of how many people become ill, and how seriously ill they become, if a specific pathogen is in the product. This is called the risk estimate. If a qualitative risk assessment has been done, the risk estimate will be a simple statement that the risk is high or low or medium. If it is a quantitative risk assessment, the risk estimate will be a number, such as predicted illnesses per annum in the population, or the probability of becoming ill from eating a serving of the product.

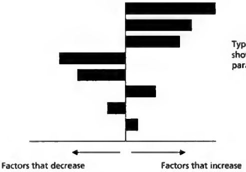
Do not forget that the main reason for doing risk assessments is so that risk managers can use the output – the risk estimates in the characterization. Therefore, the managers need to know whether there is uncertainty and variability in your estimate. A good example of the effect these two properties have is shown by the Lindqvist and Westöö (2000) study on smoked and gravad trout in Sweden. They estimated the number of annual cases by two dose response models. Method one predicted a mean of 168 cases and a range of 47–2 800 cases. Method two predicted a mean of 95 000 cases with a range of 34 000–1 600 000. The ranges reflect the uncertainty built into the predictions, and the authors list the data that should be collected to make more accurate predictions.

Another output in the risk characterization that is invaluable for risk managers is a sensitivity analysis. This analysis ranks the influence that each parameter has on the risk. Some factors increase the likelihood of illness while others decrease it. Lindqvist and Westöö found that the probability of becoming ill after eating smoked or gravad fish was most affected by:

- level of contamination (number of *L. monocytogenes* on the product);
- prevalence of contamination (percentage of servings contaminated);
- serving size (the more you eat the more likely you are to become ill);
- proportion of virulent strains of *L. monocytogenes*.

These findings help the risk manager to focus on areas that should receive priority action. If the assessors identify uncertainty within these areas, the managers may decide to invest in studies to obtain better data and reduce the uncertainty.

Some risk assessments present the sensitivity analysis as a chart with bars representing the extent of the impact each parameter has on risk. A typical chart is shown below, and because of its shape it is usually called a "Tornado chart"; each bar refers to a particular property that is correlated either with increased or decreased risk.



Typical Tornado chart showing the effect each parameter has on risk

Reality check

Whether you do a qualitative or quantitative risk assessment you must do a reality check and compare your predictions of annual illness with statistics kept by your country's Health Department. Referring to the risk assessment of Lindqvist and Westöö (2000) of listeriosis from smoked fish in Sweden, the predictions are wide-ranging. The authors state that there are around 37 cases of listeriosis each year in Sweden, from all sources, and method one (mean 168 cases) is in reasonable agreement.

3. How to use risk assessments

3.1 INTRODUCTION

There are many reasons for doing risk assessments but they all fall into three main categories:

- identifying high risk products and pathogens in your industry;
- managing risks in your industry;
- identifying where in the food chain control steps can best be applied.

In this Section we focus on each of these categories by:

- risk profiling to focus on priorities;
- integrating risk managers with risk assessors;
- linking risk assessment with HACCP.

3.2 USE 1: RISK PROFILING AN ENTIRE INDUSTRY

There is sometimes an impression that a particular food category is high risk and people tend to jump to conclusions if there is an outbreak of food poisoning. "*Must be the prawns*" they say, even though consumers ate a range of foods and there is no evidence linking the problem with any one food item. So risk profiling has great use in helping you focus on particular pathogens and products that are more likely than others to cause serious problems. Risk profiling is defined as "*a description of a food safety problem and its context developed for the purpose of identifying those elements of a hazard or risk that are relevant to risk management decisions*".

An example of a risk profile of an entire industry is provided by the Australian industry. In 2000, the Australian seafood industry began to build an Australia Seafood Standard and decided to do a risk profile as a first step. A number of hazard:product pairings were identified and a risk ranking made of each pairing (Table 9). A spreadsheet

TABLE 9

Risk rankings of hazard:product pairings of significance for the Australian seafood industry

Hazard:product pairing	Selected population	Risk ranking *
Ciguatera in reef fish	General Australian population	45
Ciguatera in reef fish	Recreational fishers, Queensland	60
Histamine in tunas and other fish	General Australian population	40
Algal biotoxin in shellfish-controlled waters	General Australian population	31
Algal biotoxin – during an algal bloom	Recreational gatherers	72
Mercury in predaceous fish	General Australian population	24
Viruses in oysters – contaminated waters	General Australian population	67
Viruses in oysters – uncontaminated waters	General Australian population	31
V. parahaemolyticus in cooked prawns	General Australian population	37
V. cholerae in cooked prawns	General Australian population	37
V. vulnificus in oysters	General Australian population	41
L. monocytogenes in cold smoked seafoods	General Australian population	39
L. monocytogenes in cold smoked seafoods	Susceptible (aged, pregnant, etc)	45
L. monocytogenes in cold smoked seafoods	Extremely susceptible (AIDS, cancer)	47
C. botulinum in canned fish	General Australian population	25
C. botulinum in vacuum packed smoked fish	General Australian population	28
Parasites in sushi/sashimi	General Australian population	31
Enteric bacteria in imported cooked shrimp	General Australian population	31
Enteric bacteria in imported cooked shrimp	Susceptible (aged, pregnant etc)	48

* Note: a change in risk ranking of six units is equivalent to a tenfold change in risk

tool called Risk Ranger was used (see Section 4), and data to complete the questions were obtained from the literature or were based on expert opinion of the risk assessors. Full details of the profile are presented in Sumner and Ross (2002), which is included in the Resource Bank.

As a result of the profiling exercise, seafoods in Australia were grouped into three risk categories:

"Low" risk category (risk ranking <32)

This category includes mercury poisoning (relative risk (RR) = 24), *Clostridium botulinum* in canned fish (RR = 25), or in vacuum-packed cold smoked fish (RR = 28), parasites in sushi/sashimi (RR = 31), viruses in shellfish from uncontaminated waters (RR=31), enteric bacteria in imported cooked shrimp (RR = 31) and algal biotoxins from controlled waters (RR = 31). There have been no documented cases of food-borne illness from any of the above hazard:product pairings in Australia.

"Medium" risk category (risk ranking 32–48)

This category includes *V. parahaemolyticus* in cooked prawns (RR = 37), *V. cholerae* in cooked prawns (RR = 37), *L. monocytogenes* in cold smoked seafoods (RR = 39), histamine fish poisoning (HFP) (RR = 40), *V. vulnificus* in oysters (RR = 41), ciguatera in the general Australian population (RR = 45), *L. monocytogenes* in susceptible (RR = 5) and extremely susceptible populations (RR = 47) and enteric bacteria in imported cooked shrimp eaten by vulnerable consumers (RR = 48).

With the exception of *V. cholerae* or enteric bacteria in imported prawns, all of these hazards have caused several outbreaks of food poisoning in Australasia.

"High" risk category (risk ranking >48)

This category includes ciguatera from recreational fishing in susceptible areas (RR=60), viruses in shellfish from contaminated waters (RR=67) and algal biotoxins from uncontrolled waters in an algal event (RR=72). All of these hazard:product combinations have caused large-scale food poisoning incidents.

Directions from the risk profile

At the end of the risk profiling exercise you will know much about your industry and will be able to make a priority listing of hazards and products that require more complete risk assessment.

The profiles also provide a focus for seafood risk managers, showing them the pathogens and products on which they should concentrate. The ways managers can approach their task is illustrated in the next section.

3.3 USE 2: RISK MANAGEMENT

When the risk assessors complete their work and present their estimates, the risk managers use the estimates to regulate (manage) the hazard. Continuing the Australian approach as an example, there are no fewer than eight risk managers who represent the various states and territories in the country. For some states and territories, the profiles alerted risk managers to hazards and products that needed urgent attention. For example:

- Exports of live reef fish to Asia and the risk of ciguatera is managed by the Australian Quarantine and Inspection Service (AQIS).
- A huge recreational fishery for which ciguatera is a risk managed by SafeFood Queensland.
- The risk of enteric pathogens in oysters is managed by several state authorities.
- The risk of uncontrolled gathering of clams on remote beaches during an algal event is managed by various state authorities.

The above examples are presented to show how risk managers in different parts of a country need to focus on specific, regional risks. Of course, risk managers interface with all stakeholders in risk communication phases, but in the end it is the managers who must make the regulatory decisions to manage specific risks. Risk Ranger is a useful tool for risk managers and following is an example of how they could use the tool.

3.4 RISK MANAGEMENT CASE STUDY: ENTERIC VIRUSES IN OYSTERS

Viral contamination of oysters is an enduring cause of illness in many countries. Viruses most commonly associated with outbreaks are Norwalk and noroviruses (also termed small round structured viruses [SRSVs]) and HAV. Illnesses result from contamination of oyster leases by human sewage during heavy rainfall events. Most countries have a classification system for oyster growing areas based on the likelihood of their becoming contaminated by human sewage. The classification is linked with activities such as:

- depuration;
- relaying contaminated oysters in "clean" waters;
- stopping of harvest after rainfall events;
- management strategies intended to reduce viral contaminants to an acceptable level.

Interestingly, while HACCP has become the preferred risk management for the food industry, virus control by depuration and relaying are processes that have not been validated as critical control points (Lees, 2000).

As populations increase, traditional oyster leases become encroached by human habitation, and this results in contamination of oyster beds during rainfall events. One obvious course of action open to you, as a risk manager, is to prevent oysters being harvested in areas that are subject to regular contamination with human faeces (so-called "restricted" areas) by ordering their permanent closure. However, if you try to do this you will find that food safety competes with political, social and economic issues. Clearly it would be advantageous if you could use straightforward risk estimates to explain the bases of your risk management decisions.

One approach is to use Risk Ranger to compare the probability of contracting Hepatitis A after consuming oysters from waters that are never subjected to contamination with human faeces, with oysters from waters that often become contaminated after heavy rainfall. Table 10 contains all the inputs to Risk Ranger for the two scenarios.

A number of assumptions are made:

- Prevalence of HAV in oysters from pristine waters is 0.001 percent.
- In oysters harvested from contaminated waters prevalence is 15 percent. This was the prevalence of contamination in oysters one month after a Hepatitis A outbreak in Australia in 1997 (Conaty *et al.*, 2000; Grohmann, 1997).
- At least 1 000 units of HAV are required to cause illness in the average consumer (Rose and Sobsey, 1993).
- This level will already exist in oysters from polluted waters.
- A 100x increase is required to reach an infective level in oysters from "clean" waters.
- Consumption size is a serving of six oysters (about 100 g).
- In considering consumption from uncontaminated waters, some (25 percent) of the population were assumed to consume a monthly serving.
- In the scenario where oysters were contaminated with HAV, most (75 percent) of a localized population of 100 000 were assumed to consume a weekly serving.

If these data are input to Risk Ranger, there is a great difference in risk ranking and predicted illnesses. Oysters from clean waters have a risk ranking of 20 and predicted illnesses of 1 every 20 years. By contrast, oysters from polluted waters have a risk ranking of 70, which is 100 000 000 times increased risk compared with oysters from clean waters. It is predicted that all 100 000 consumers will become ill.

TABLE 10
Risk ranking of oysters consumed raw from waters that are never polluted and those that are subject to human faecal contamination

Risk criteria	"Clean" waters	Waters subject to pollution
Dose and severity		
Hazard severity	Mild – sometimes requires medical attention	Mild – sometimes requires medical attention
Susceptibility	General – all population	General – all population
Probability of exposure		
Frequency of consumption	Weekly	Weekly
Proportion consuming	Some (25%)	Some (25%)
Size of population	1 900 0000	100 000
Probability of contamination		
Probability of raw product contaminated	0.001%	15%
Effect of processing	No effect	No effect
Possibility of recontamination	None	None
Post-process control	Not relevant	Not relevant
Increase to infective dose	100 times	None
Further cooking before eating	Not effective in reducing hazard	Not effective in reducing hazard
Estimated annual illnesses	1 every 20 years	100 000
Risk ranking (0–100)*	20	70

* Note: a change in risk ranking of six units is equivalent to a tenfold change in risk

Clearly, your task as risk manager is made more straightforward by Risk Ranger predictions. Now, the responsibility is moved from resting solely on your shoulders, to being shared with stakeholders who must choose whether to continue with increased risk predicted illnesses.

In summary, the risk characterization model allows a rapid "broad brush" estimation of risk, which will assist risk managers to prioritize hazard:product pairings for more intensive risk assessment studies. It also allows timely response to "what if" scenarios, which will benefit risk managers and communicators, alike.

3.5 USE 3: RISK ASSESSMENT AND HACCP

Since the 1980s, HACCP has become an important part of the food business as a hazard management system. The first HACCP principle requires assessment of whether the hazard is "significant", which implies some assessment of risk (severity + likelihood), which raises the question *"are HACCP and risk assessment linked?"* Most people would answer *"Yes, they are linked but I cannot quite work out how"*. Here is an example of how HACCP and risk assessment can go together. Note that the example is entirely hypothetical and the photographs (below) do not refer to any problem with transshipping tuna.

Your Fisheries Department receives the following photographs by electronic mail from the regulatory authorities in the importing country. One of their inspectors spent all day in transit, and observed several pallets of chilled tuna in cartons that sat on the tarmac for eight hours. The inspector was able to identify the company, which is your largest exporter of tuna. When it arrived in the importing country, the entire consignment was confiscated and an immediate embargo placed on your exports.

Initial investigation

You are charged with fixing the problem. The importing country stipulates that you must make "risk-based" decisions in solving the problem. Since exports have been banned, your supervisor wants the problem fixed very quickly.

You contact the exporting company and learn that they routinely include a data logger in each consignment. The exporter's agents in the importing country are able to locate the logger and download the data. The temperature:time trace (Figure 1)

08.00 at the transit airport where product from your country changes flights. The scheduled flight has been cancelled and several tonnes of chilled tuna are left on the tarmac until another flight arrives. The ground temperature is 33 °C

16.30 at the transit airport. Product is being loaded on a rescheduled flight. During the day, maximum ground temperature reaches 40 °C

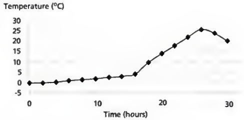
indicates substantial product warming. The agents tell you the carton was on the outside of the stack, which means it measured worst-case product warming of product in the consignment.

Estimating growth on tuna

By using predictive microbiology you can estimate the growth of histamine-producers on a product in each outer carton. Table 11 contains growth rates at each temperature

FIGURE 1

Product temperature at site of microbiological concern during transit of chilled tuna



(from the literature), and by multiplying by the length of time the product was in that temperature zone you can calculate potential growth. You can do this by using data from Figure 1.

TABLE 11
Potential growth of histamine-producers on tuna abused at high temperatures

Temperature zone	Generation time (hours)	Time in zone (hours)	Potential growth (generations)
10–15	3	3	1
15–20	1.5	3	2
20–25	1.0	5	5
25–30	0.75	3	4

Increased risk at warm temperatures

The steep rise in temperature while product is exposed to direct sunlight sees the surfaces of microbiological concern rise to 26 °C before loading into the air-conditioned hold of the airliner stabilizes temperature. Around 12 generations (3–4 log growth) occurred during the storage on tarmac and this can be inputed to Risk Ranger to assess the increased risk (Table 12).

The total consignment was more than 3 tonnes, of which 1 tonne was severely temperature-abused, and you concentrate on this portion of the consignment. There are around 10 000 servings of 100 g each serving that have been temperature-abused. Calculations indicate that histamine-producers will have grown to around 10 000/g of product. If someone consumed 100 g of this product they would ingest the equivalent of the histamine produced by one million bacteria/g. It is assumed that if histamine-producers reach 100 000 000/g they will produce sufficient histamine to cause illness. Thus a further increase of 100x is needed for a toxic level.

All the above data are input to Risk Ranger. The risk ranking as shown in Table 12 is 67, and around 5 000 illnesses are predicted from the 10 000 servings, which will be eaten over a period of about one week.

TABLE 12
Semi-quantitative risk characterization of HFP following consumption of tuna that has been temperature-abused

Risk criteria	Product that has undergone temperature abuse
Dose and severity	
Hazard severity	Mild – sometimes requires medical attention
Susceptibility	General – all population
Probability of exposure	
Frequency of consumption	Weekly
Proportion consuming	All (100%)
Size of population	10 000
Probability of contamination	
Probability of raw product contaminated	0.1%
Effect of processing	Chilled storage prevents growth of histamine producing bacteria
Possibility of recontamination	None
Post-process control	Poor (>3 log increase)
Increase to infective dose	100x
Further cooking before eating	Not effective in reducing hazard
Predicted illnesses	5 200
Risk ranking (0–100)	67

Integrating risk assessment with HACCP

You examine the HACCP plans of each company exporting tuna. A typical plan is shown in Table 13 and does not take into account the possibility that product will be held up if flights are delayed. Your supervisor informs you that a high-level delegation is coming from the importing country to review your risk assessments and integration with HACCP. He indicates that they will need to see a great deal of rigour surrounding

TABLE 13
Current HACCP plan form for control of histamine formation during the air journey

Critical Control Point (CCP)	Significant Hazards	Critical Limits for each Preventive Measure	Monitoring				Corrective Action	Records	Verification
			What	How	Frequency	Who			
CCP 6: Air freight	Histamine formation	Fish no warmer than 5 °C on arrival	Product temperature	Temperature logger	One logger per lot	Importer	Accept/reject fish. Re-ice	Data logger	Check on return of logger

TABLE 14
Revised HACCP plan form for temperature control of product at the transit airport

Critical Control Point (CCP)	Significant Hazards	Critical Limits for each Preventive Measure	Monitoring				Corrective Action	Records	Verification
			What	How	Frequency	Who			
CCP 6: Transit	Histamine formation	Store in air-conditioned hanger for <3 hours ("normal" transit)	Location	Visual, and record times on Consignment Sheet	Every consignment	Airport agent	Agent arranges immediate transfer to air-conditioned hanger	Consignment sheet	Consignment sheet faxed to company
		Store in air-conditioned hanger for >3 hours ("delayed" transit)	Air temperature	Data logger	Every storage when there is a delay	Airport agent	Agent logs ambient temperature and storage time	Consignment sheet Data logger	Consignment sheet faxed to company Data logger downloaded and information emailed to company
CCP 7: Arrival	Histamine formation	Fish no warmer than 5 °C	Product temperature	Temperature logger in marked carton	One logger per lot	Importer	Accept/reject fish. Re-ice	Data logger	Check on return of logger

the transit airport. It seems flight delays are not uncommon, which turns out to be the only reason your exporters include a data logger, so they have evidence against the airlines in an insurance claim.

Clearly there is the need for cold storage at the transit airport so that product can be quickly taken from the furnace-heat of the tarmac. Enquiries indicate that there is not much cold storage space, but there is a large air-conditioned hanger at 10–15 °C, which is used for holding flowers, fruits and vegetables. Pallets can be quickly driven there until the transit flight arrives. You simulate these storage conditions in your country by using data loggers and find that product does not rise above 5 °C even after 12 hours storage at 10–15 °C. You use this study as part of the HACCP validation for the visiting delegation.

Your next task is to set up a system at the airport that ensures product is moved to cool storage if there is a flight delay. This involves:

- employing an agent at the transit airport to handle all consignments from your country;
- setting up a record of arrival time and departure time of each consignment;
- placing all consignments in air conditioned hanger until the connecting flight begins loading;
- fixing a single-use data logger to the outside of a pallet stack to monitor ambient temperature and time of delay;
- downloading data to the exporting company for verification of control of air temperature.

The systems you set up are fixed in the new HACCP plan for air transit control (Table 14).

By using Risk Ranger you can quickly estimate changes in risk of becoming ill from HFP with changes to the HACCP plan. The plan as set out in Table 12 has a risk ranking of 67, because flight delays lead to a loss of temperature control. The HACCP plan as set out in Table 14 reduced risk ranking to 12. The reduction in risk is on the order of 100 million times.

This gives you considerable documentation to set before the delegation and, if they request different scenarios, you can quickly simulate them using Risk Ranger.

Your risk assessment work has generated a good deal of information on how your export tuna fishery operates, and you are now able to bring HACCP plans onto a true risk basis.

4. Risk Ranger

4.1 BACKGROUND TO DEVELOPING RISK RANGER

If you are a risk manager you need to be able to compare and prioritize risks. There are a number of decision support tools that will guide you on whether a pathogen might be an important hazard in a given food or food process combination. These include various semi-quantitative scoring systems such as those by Corlett and Pierson (1992), shown in Table 15 and by Huss, Reilly and Ben Embarek (2000), which is illustrated in Table 16.

While the above approaches are able to categorize risk and direct broad mitigation strategies, neither can be used to assess an as yet undocumented risk, or to measure the effect of contributions to risk of individual factors. These schemes do not focus on the steps or variables where control could most effectively be applied.

Risk Ranger is a simple and accessible food safety risk calculation tool intended to help determine relative risks from various product/pathogen/processing combinations and is presented in Microsoft® Excel spreadsheet software. In particular, it is intended to make the techniques of food safety risk assessment more accessible to non-expert users, and to users with limited resources, both as a decision-aid and an educational tool.

Risk Ranger incorporates all factors that affect the risk from a hazard in a particular commodity including:

- severity of the hazard and susceptibility of the population of interest;
- likelihood of a disease-causing dose of the hazard being present in a meal;
- number of meals consumed by a population of interest in a given period of time.

A number of factors affect each of the above.

Disease severity is affected by:

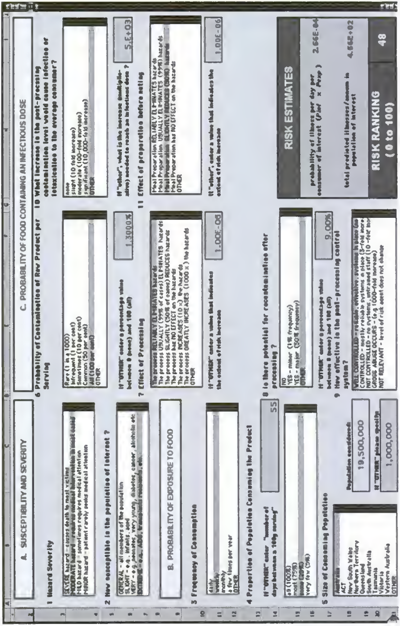
- intrinsic features of the pathogen/toxin;
- susceptibility of the consumer.

TABLE 15
Hazard classification of Corlett and Pierson (1992)

Hazard	Risk characteristics
A	Special class restricted for at-risk populations, e.g. the aged, immunocompromised, infants
B	Product contains sensitive ingredients
C	Process has no step which destroys sensitive organisms
D	Product is subject to recontamination between processing and packaging
E	Potential for abuse by distributor or consumer, which could render the product hazardous
F	Product is consumed without further process to kill micro-organisms

TABLE 16
Qualitative risk assessment based on the process of Huss, Reilly and Ben Embarek (2000)

Risk criteria	Raw molluscan shellfish	Canned fish	Dried fish
Bad safety record	+	+	-
No critical control point for the hazard	+	-	-
Possibility of contamination or recontamination	+	+	-
Abusive handling possible	+	-	-
Growth of pathogens can occur	+	-	-
No terminal heating step	+	+	+
Risk category	High	Low	No risk



The Risk Ranger shop front

Exposure to the food will depend on how much is consumed by the population of interest, how frequently they consume the food and the size of the population exposed.

Probability of exposure to an infectious dose will depend on:

- serving size;
- probability of contamination in the raw product;
- initial level of contamination;
- probability of contamination at subsequent stages in the farm-to-fork chain;
- changes in the level of the hazard during the journey from farm to fork, including simple concentration and dilution, growth or inactivation of pathogens.

4.2 USER INTERFACE – THE RISK RANGER SHOP FRONT

Risk Ranger has a "shop front" with a series of list boxes into which you enter information using your computer's mouse. In total, you need to answer 11 questions, and a mathematical model then converts each answer to a numerical value or 'weighting'. The weightings are detailed in the paper by Ross and Sumner (2002). Some of the weightings are arbitrary, while others are based on known mathematical relationships, e.g. from days to weeks, or years. To help you make your responses as objective as possible, and to maintain transparency of the model, descriptions are provided and many of the weighting factors are specified. As well, in some cases, if the options provided do not accurately reflect the situation being modelled, you can enter a numerical value by using the "Other".

Behind the shop front is the model, developed in Microsoft® Excel software, using standard mathematical and logical functions. The list box macro tool is used to automate much of the conversion from qualitative inputs to quantities for calculations. For each selection you make from the range of options, the software converts that selection into a numerical value.

4.3 HOW TO USE RISK RANGER

To help you understand how Risk Ranger works, let us cover each of the 11 questions in turn and explain the scientific background behind each of them.

Question 1: Hazard severity

You are offered four choices, based on the severity of the symptoms caused by the hazard. In the Table 17 are our ideas on how seafood hazards fit into the descriptions.

If you click on the coding tab at the bottom left side of Risk Ranger you will switch to the codings for each question. You will see there is a ten-times difference in severity between each category of hazard. This is an arbitrary difference.

You may not agree with the descriptions and the way hazards are linked with them in Table 17. For example, you might say that most cases of *L. monocytogenes*, enterohaemorrhagic *Escherichia coli* (EHEC) and *V. vulnificus* do not require medical intervention, and it is only for susceptible groups that the description is true. Similarly, in some cases, *Salmonella* can be a serious infection with long-lasting consequences

TABLE 17
Associating hazards with Risk Ranger descriptions at Question 1

Description	Consequences of the hazard	Hazard
Severe	Death in most cases	Tetrodotoxin, Botulinum toxin
Moderate	Most cases require medical treatment	*Listeria monocytogenes, Vibrio vulnificus, Vibrio cholerae*, EHEC
Mild	Sometimes medical treatment is needed	*Vibrio parahaemolyticus*, Hepatitis A, Norwalk-like viruses, histamine, ciguatera, algal biotoxins, *Salmonella*
Minor	Medical treatment rarely required	*Staphylococcus aureus, Clostridium perfringens*

such as reactive arthritis. But Mead *et al.* (1999) state that, in the United States, there are probably 38 times more cases of salmonellosis than those that are reported, so for most people *Salmonella* infection obviously resolves itself without entering the medical system. By contrast, at least 50 percent of listeriosis cases are reported. And this ratio is probably higher for EHEC.

This is one limitation of Risk Ranger and, if you believe a description is wrong for the specific country or system you are working on, then by all means move the hazard to the category of your choice.

Question 2: Susceptibility of the population in which you are interested

Risk Ranger allows you to select one of four populations that vary in their level of susceptibility. Groups that are slightly (five times) more susceptible than the general population to food-borne hazards are small children (1–5 years old) and people over 65 years old. In the "very susceptible" category are newborn babies, children under one year and people with conditions such as diabetes, cancer and liver damage, which predispose them to infectious diseases. They are rated 30 times more susceptible than the general population. People with AIDS or who are recovering from transplant surgery have very impaired immune systems, which place them in the "extremely susceptible" category, 200 times more likely to succumb to hazards than the general population. The various weightings, 5x, 30x and 200x, are loosely based on the relative susceptibility of each population subgroup to *Listeria monocytogenes*. Consequently, they may give unexpected results if applied to hazards that all people are more or less equally susceptible to, for example, *S. aureus* enterotoxin. If you want more details of the reasons for these weightings, see Ross and Sumner (2002).

When you select this subpopulation, Risk Ranger automatically makes changes in two other questions:

- In Question 5, the size of the subpopulation is modified to the correct proportion of the total population.
- In Question 10, the increase to infectious dose is automatically adjusted to take into account the increased vulnerability of subgroups.

Absolute risk is based on the population size, the proportion of the population consuming the food and how frequently people eat the food, and this information is selected in Questions 3–5.

Question 3: Frequency of consumption

Obviously, the more often we face a hazard, the more likely we are to be affected by it, and this question reflects the popularity of a seafood product. The selections you can make are set in absolute terms, based on annual consumption, and this is obvious from the coding used.

Question 4: Proportion of population consuming the product

The proportion consuming the product is set for all (100 percent), most (75 percent), some (25 percent) and a few (5 percent) of the population.

It is best to link your selections for Questions 3 and 4, such as "*Everyone eats the product daily*", which might apply to consumption of reef fish by the population living on a Pacific atoll. By contrast you may select "*Some people (25 percent) eat the product weekly*", which might apply to oyster consumption in a European country.

You can answer Questions 3 and 4 using either of two methods:

- using consumer survey data that gives you a very good idea of consumption pattern;
- calculating the amount consumed from product landing or harvest and then dividing by the population you think eats that product. Obviously you need to make an assumption here and to state what your assumption is.

Question 5: Size of consuming population

Risk Ranger has several country populations already programmed into Question 5 and, if you want to select another country just select "Other" in the list box, and type the population of that country in the "Other" box. Alternately, if you want to make the list box specific, click the tab for CODINGS and you will see instructions on how to put in your own populations.

If you select a subpopulation from the general population in Question 2, Risk Ranger automatically estimates the number in that category. Because Risk Ranger was developed in Australia, the proportions refer to that country, and they also fit many other countries with similar lifestyles, particularly in North America and Europe. However, you may need to recalibrate the coding for this question for countries in which certain diseases are rampant, e.g. for countries with a high prevalence of AIDS.

Question 6: Probability that a serving of raw product is contaminated

To answer this question you obviously need data. For example, if you were considering viruses in oysters, it is important to know how many servings have sufficient viruses to infect you. Similarly, you may want to know how prevalent is a bacterial pathogen, such as *Salmonella*, in raw shrimp. If you have data from a properly designed survey you can insert the exact level by selecting "Other" in the list box, then typing the percentage in the box below. Alternatively you may not have an accurate idea on proportion contaminated and, in this case, you can select the most appropriate category in the list box.

Question 7: Effect of processing

To answer this question you need to know about the process and how it affects the hazard. Here are some examples:

- If you are considering viruses in oysters to be consumed raw, their numbers are not affected by processes such as shucking or storage, so you select "No effect on the hazard". The same selection is made for ciguatera in reef fish, because the level of toxin is not affected by the process.
- If you are considering *Salmonella* in cooked shrimp, the cooking process is sufficient to kill all of the bacteria, so select "Reliably eliminates hazard". The same selection is made for *Listeria monocytogenes* in hot smoking and for *Clostridium botulinum* in canning.
- If you hold tuna from warm waters without ice, the bacteria will produce histamine at a rate that depends on temperature and time. You select either "Increases the hazard" or "Greatly increases the hazard", depending on the extent of temperature abuse.
- If you freeze seafood, a proportion of bacteria are likely to die – perhaps as many as 50 percent – and this option can be selected.

Question 8: Potential for recontamination after processing

Recontamination is particularly important for those products that have received heat treatment during the process. Such products have low bacterial levels and any contaminant will be able to grow with little competition. Examples of where recontamination is important include:

- cooked, peeled shrimp recontaminated with *Staphylococcus aureus* from the hands or noses of food handlers;
- hot smoked salmon recontaminated during slicing and packing with *L. monocytogenes* from the environment;
- canned seafood recontaminated through a leaking seam with *Clostridium botulinum* from seawater used in cooling.

To answer Question 8 you really need data generated from surveys, and this can be typed in the "Other" box. If you do not have data on recontamination you can make an assumption based on observation or on comparison with similar processes that have been surveyed in countries with conditions similar to your own. For example, if you observe operators peeling shrimp with their bare bands you can predict that up to 50 percent of the product will be contaminated, because 30–50 percent of food handlers carry *S. aureus* on their hands and nose.

Question 9: How effective is post-processing control?

In this question you need to know how the product is handled during storage, distribution and retailing. Also you need to know something about the hazard and how it responds to those controls. Here are some examples:

- Bacterial pathogens in frozen seafood cannot increase, and may even die, so select "Well controlled" from the list box.
- The population of viruses in oysters will remain static during storage, so select "Not relevant".
- In smoked seafoods stored at 4–5 °C, *L. monocytogenes* will be able to multiply. If the shelf-life is long (4–6 weeks) growth will be considerable, so select "Gross abuse occurs".
- In chilled, ready-to-eat seafoods such as cooked shrimp, stored at 4–5 °C, *L. monocytogenes* will grow, but because the shelf-life is only short, increase in growth will not be great, so select "Controlled".

Question 10: What level of increase is needed to cause illness?

To answer this question you need to know something about the amount of the hazard that would be required to cause illness. Table 18 presents some data on the number of organisms it takes to make a healthy person ill. The numbers are given for a 100 g serving, so the count/g of food is 100x lower. It is with great trepidation that these numbers are presented here because not every microbiologist will agree with them. These numbers should be regarded as guidelines, and do not forget that vulnerable consumers require much lower doses to make them ill. And if you believe a number is wrong and have good evidence, please use your own data at Question 10.

TABLE 18
Levels of pathogenic bacteria that are likely to cause illness in healthy people

Organism	Infective dose in a 100 g serving
Salmonella	10 000 000
Listeria	10 000 000 000
Viruses (Hepatitis A, Norwalk)	10–100
Enterohaemorrhagic *E. coli*, *Shigella*	1 000
Staphylococcus aureus	100 000 000

Knowing the number of micro-organisms surviving after processing, divide this number into the number required to cause illness (from Table 18 or more updated data) and you have the answer to Question 10.

For example, if you are considering Hepatitis A contamination in oysters, then select "None", because the infective dose is already contained in the serving. The same answer is selected for ciguatera, since the toxin is already present at processing.

If you are considering *L. monocytogenes* in smoked seafood, you probably will not know the contamination level after processing and recontamination. The literature tells us that contamination level will probably not exceed 10 g, so if we consume 100 g there are 1 000 cells in our serving just after processing. If we assume that we need around 10 000 000 000 to make us ill, the increase to infective dose is 10 000 000-fold and we can enter that in the "Other" box at Question 10.

Question 11: Effect of meal preparation

This question considers the form of cooking and preparation for cooking. Here are some examples of how you can answer Question 11:

- for cooked shrimp kept chilled until consumption, select "No effect";
- for histamine in tuna, staphylococcal toxin in cooked crustaceans, ciguatera in reef fish, or algal biotoxins in bivalves, select "No effect" because the toxins are heat-stable;
- for viruses in oysters eaten raw, select "No effect" but, if cooked lightly in the half-shell, select "Slightly reduces" the hazard;
- for raw seafood contaminated with pathogenic bacteria or viruses that will be thoroughly cooked, select "Reliably eliminates".

4.4 RISK ESTIMATES

Risk Ranger combines the factors in Questions 1–11, including some logical tests to generate three estimates of risk:

- risk ranking – a score between 0–100;
- predicted annual illnesses in the population you selected;
- probability of illness per day in target population;

Full details of the logic and equations leading to the risk estimates are shown in the paper by Ross and Sumner (2002), which is included in the Resources Bank.

Risk ranking

The risk ranking value is scaled logarithmically between 0 and 100. The former (Risk Ranger = 0) is equated to a probability of food-borne illness of less than, or equal to, one case per 10 billion people (greater than current global population) per 100 years. At the upper limit (risk ranking = 100), every member of the population eats a meal that contains a lethal dose of the hazard every day. A risk ranking change of 6 corresponds to a tenfold difference in the absolute risk. Thus an increase in risk ranking from 36 to 48 means that the risk increases 100-times.

Predicted annual illness

Risk Ranger estimates the total number of illnesses in the population you select at Question 5. Obviously, the higher the risk ranking, the greater the proportion of the population that will become ill. The absolute numbers of illnesses, however, will depend on the population size.

Probability of illness per day in target population

Risk Ranger targets the proportion of the population that you select at Question 2. Risk ranking remains the same, irrespective of whether you are considering the general population, or a highly susceptible subpopulation. But the probability of illness increases in the target population. This output tells you where illness is focused.

4.5 EVALUATING RISK RANGER

To evaluate the performance of the tool, the authors modelled several scenarios and compared the results with actual data or with other risk assessments. In the first evaluation, conditions leading to an outbreak of Hepatitis A from consumption of oysters in Australia in 1997 were simulated using the model and compared with the epidemiological data reported by Conaty *et al.* (2000). In the second evaluation, the data and assumptions of the quantitative risk assessment of Cassin *et al.* (1998) for the risk of illness from enterohaemorrhagic *E. coli* due to consumption of hamburgers in North American culture were used to derive answers to the questions of the risk assessment spreadsheet. The results of both assessments were compared and are

detailed in Ross and Sumner (2002). In general, Risk Ranger predicted illness of the same order of magnitude as in the actual events.

4.6 HOW RISK RANGER CAN BE USED

Risk ranger was originally developed as a means of quickly assessing the performance of various conceptual models for food safety risk assessment. However, it is also a useful tool for risk assessment and risk communication. It can be used by risk managers and others without extensive experience in risk modelling:

- as a training and risk communication aid;
- to develop risk assessments;
- to determine data needs;
- as a simple and quick means to develop a first estimate of relative risk.

Tools such as this can help managers to think about how risks arise and change and to help to decide where interventions might be applied with success.

4.7 LET US WORK THROUGH SOME EXAMPLES

Working through some examples together will help you see how Risk Ranger is used.

Let us use consumption of chilled, hot-smoked salmon contaminated with *L. monocytogenes* in the United States. For more than ten years the United States risk management strategy has been to operate zero tolerance for this organism in this product (in a 25/g sample), reflecting the seriousness that the risk manager (Food and Drug Administration) ascribes to this hazard:product pairing.

We can summarize the inputs in Table 19 and you should open Risk Ranger and work through the inputs for the general population. You will see that the Risk Ranking is 41 with predicted illnesses of 400 per annum from the United States population of 270 million. The probability of illness per day per consumer in the general population is 8^{-8}.

Important questions and assumptions are:

Question 7, where we assume that hot smoking eliminates all *L. monocytogenes*.

Question 8, where we assume first that 1 percent of servings are recontaminated and second that the level of recontamination is 0.1 cell/g (10 cells/serving).

Question 9, where we assume the shelf-life at around 5 °C is long (several weeks in the distribution and retailing chain) and the population increases to 100/g (10 000/serving).

Question 10, where we assume that the infective dose for the general population is 10 000 000/g (10 000 000 000/serving). So for Question 10, you need to select "Other" and insert 1 000 000 for the increase needed for an infective dose.

Now let us consider the effect of contaminated smoked salmon on a more susceptible subpopulation, the very young and very old. When you select this subpopulation, Risk Ranger automatically makes changes in two other questions:

- In Question 5, the size of the subpopulation is selected. In the United States this group comprises around 50 million individuals.
- In Question 10, the increase to infectious dose is automatically adjusted. You do not need to make any change – Risk Ranger does it for you.

The consumption frequency remains the same, as do the contamination levels in raw product and the effect of processing, recontamination and post-process control. Risk Ranking remains the same as for the general population; the number of illnesses falls slightly to around 350 per annum and the probability of illness per day in this vulnerable group is 2^{-6}. The latter two outputs tell you that the vulnerable subpopulation bears almost all the risk of illness with 75 percent of all listerioses and much higher probability of illness on any one day.

Reality check

Let us do a reality check on listeriosis in the United States to see if the annual illnesses we are predicting from Risk Ranger are approximately correct. Statistics indicate around 1 000 cases notified each year (4 cases/million population), which, when we take into account under-reporting, extends to around 2 000 cases. Risk Ranger predicts around 400 annual cases due to the consumption of smoked salmon, a prediction which is in an acceptable range.

Summary

The main reason for doing this exercise is to help you understand how Risk Ranger automatically selects subpopulations for you, plus how important it is to understand how to calculate the increase to infectious dose (Question 10). The more you understand a food process and the behaviour of the target pathogen, the better outputs you will get from Risk Ranger.

TABLE 19

Risk Ranger inputs for *L. monocytogenes* in chilled, hot-smoked salmon in the United States

Risk criteria	General population	Very young and old
Dose and severity		
Hazard severity	Moderate – usually requires medical attention	Moderate – usually requires medical attention
Susceptibility	General – all population	Very young and very old
Probability of exposure		
Frequency of consumption	Few times a year	Few times a year
Proportion consuming	Few (5%)	Few (5%)
Size of population	270 million	ca 50 million
Probability of contamination		
Probability of raw product contaminated	10%	10%
Effect of processing	Hot smoking eliminates all contaminants	Hot smoking eliminates all contaminants
Possibility of recontamination	Minor (1%)	Minor (1%)
Post-process control	Poor (>3 log increase)	Poor (>3 log increase)
Increase to infective dose	1 000 000x	1 000 000x
Further cooking before eating	Not effective in reducing hazard	Not effective in reducing hazard
Predicted annual illness in the population considered	400	365
Probability of illness per day per consumer of interest	8.22×10^{-8}	2.47×10^{-6}
Risk ranking (0–100)	41	41

5. Examples of risk assessments

5.1 INTRODUCTION

There are three types of risk assessment outputs:

- Qualitative risk assessments
- Semi-quantitative risk assessments
- Quantitative risk assessments

In this section, we give an example of each type of assessment. In each you are nominated as leader of the risk assessment team and, from time to time, background information is provided in boxes. For example, we point you towards review articles, which can quickly give you information on a hazard that causes illness from seafoods. These reviews are included in the Resources Bank.

In normal text we include typical material, which is included in a risk assessment. While each assessment uses fictitious information for the exposure assessment module, this gives you some idea of how to generate exposure information.

For characterizing risk, a semi-quantitative tool called Risk Ranger is used. It is a versatile tool and you can find how to use it in Section 4. In the text, all inputs to Risk Ranger are contained in boxes.

Risk assessment examples

The following four examples have been chosen and developed to show you how risk assessment work can help you solve food safety problems with specific fisheries.

i. Qualitative risk assessment: mercury in fish

Mercury contamination of seafoods occurred in Japan in the 1950s when several hundred people suffered terrible symptoms, which included brain damage. Since this time, mercury intake has been monitored in many countries and the problem managed by limiting consumption of large predaceous fish, such as sharks. More recently, research has suggested that, in its early stages, the human foetus may be susceptible to the effects of mercury, with symptoms such as impaired learning ability emerging in childhood.

Because there are, at present, no data on levels of mercury in the diet that may cause childhood difficulties, the hazard: product pairing is best evaluated in a qualitative risk assessment.

ii. Semi-quantitative risk assessment: ciguatera in reef fish

With the spread of air travel, remote communities are now able to use tourist flights to freight seafoods to destinations where reef fish are considered delicacies. Some species are extremely valuable. In Hong Kong Special Administrative Region, China, for example, a 1 kg (plate-size) live coral trout is worth more than $30 to the exporter. Unfortunately, some species from tropical and subtropical waters can accumulate ciguatoxin in their muscle and ciguatera fish poisoning (CFP) is the most prevalent illness caused from consumption of finfish.

In this example, your country, a series of atolls in the south Pacific, has the opportunity to export reef fish to nearby countries. Unfortunately, a number of locations are endemic for ciguatera, and CFP occurs among tourists and your own people. You are required to do a risk assessment in a very short time frame and the

example points the way to doing this, with a semi-quantitative risk assessment using Risk Ranger to generate a risk ranking plus predicted annual illnesses.

iii. Semi-quantitative risk assessment: histamine fish poisoning
Histamine fish poisoning (HFP) is another cause of illness from particular species of finfish. Your country has an export industry based on fish caught by small boats that troll for tuna on overnight trips. Traditionally these boats have not carried ice but, after product from your country has been implicated in an outbreak of HFP in the importing country, you are required to do a risk assessment. Your country lacks the laboratory facilities or resources to provide backup, so you rely on the predictive microbiology approach and gather information on temperatures and times of product throughout the catching-processing-transport and marketing stages.

The assessment leads to a risk management and risk communication exercise by stakeholders in your country after which there is follow-up assessment work that you must do.

iv. Quantitative risk assessment: Vibrio parahaemolyticus ***on oysters***
In 1997 and 1998 there were large outbreaks of food poisoning from consumption of oysters in North America in which *Vibrio parahaemolyticus* was the cause. Your country is an exporter of oysters to the United States and, after that country does a risk assessment of *V. parahaemolyticus* in oysters, there is pressure on your country to provide risk estimates for product that you are exporting to the United States. You decide to use the United States risk assessment model and to insert data from your own country. In this example, we follow how your team does the risk assessment and then communicates the estimates to authorities in the importing country.

5.2 HOW TO PERFORM A QUALITATIVE RISK ASSESSMENT: MERCURY IN SEAFOOD

The situation

There are reports that methyl mercury (MeHg) can damage the foetus during its early stages of development.

The Health Department in your country has become concerned about the possible effects of MeHg on the foetus during the early stages of its development.

Seafood consumption patterns in your country indicate that several high-mercury species are consumed, including sharks and billfishes.

Because of time constraints the risk managers in the Health Department require you to complete a qualitative risk assessment within one month of mercury intake from seafood in your country.

Available to you are seafood catch statistics, which tell you the quantity of high-mercury fish that are landed in your country, and there are also two research reports on mercury levels.

Based on the outcomes of the assessment, the managers will set tolerable intakes for pregnant women.

5.2.1 Purpose of the assessment

The purpose of the assessment is to estimate the risk of mercury poisoning to the foetus. The risk estimate will be qualitative.

5.2.2 Hazard identification

The only documented account of mercury poisoning involving seafoods occurred in people living around Minamata Bay in Japan during the 1950s. In all, there were more

than 700 cases of poisoning and 46 deaths with victims suffering severe mental and neurological conditions.

Low levels of mercury are naturally present in the environment and in all foods. Inorganic mercury is poorly absorbed via the diet, but in aquatic environments bacteria can convert inorganic mercury to MeHg, which is readily absorbed by the human body. MeHg is accumulated in the aquatic food chains, so all fish contain it in their muscle tissue. Predatory fish or mammals (particularly whales) at the top of the food web have the largest amounts.

Mercury levels in most commercially harvested oceanic fish are <0.5 mg/kg MeHg, but some large predators, such as sharks, marlin and swordfish, may have higher levels. Numerous studies have shown that nearly all the human exposure to MeHg occurs via seafood (predominantly finfish) consumption. Therefore individuals who regularly consume large amounts of fish (particularly those fish with high mercury levels) could be exposed to high levels of mercury (FDA, 1994; National Academy of Sciences, 2000).

Farmed finfish are likely to have lower levels of MeHg because they are generally fed formulated diets that should have low mercury content. As well, mercury accumulates in fish during their lifetime, and tissue concentrations are greater in older and larger fish. Since farmed fish are usually harvested young, they would be expected to have low tissue concentrations (FAO/NACA/WHO, 1999).

Nearly all the human exposure to MeHg occurs via fish consumption. There are two exceptions: accidental releases (industrial processes) and mercury used in tooth filling amalgams (Richardson, 1995).

5.2.3 Hazard characterization

Your task

You need to read some reviews on the effect of MeHg on adults and foetuses. Some are listed as references in the Resources Bank.

You will find that there are widely different views on how much mercury is safe to eat in our intake of seafood. Since these views are held by respected bodies such as FAO/WHO, the National Academy of Sciences (NAS, USA), the Environmental Protection Agency (EPA, USA), the best way to resolve any discrepancies is work with their recommendations

Illness caused from high-level exposure

In 2000, the NAS in the United States reviewed mercury in foods. MeHg obtained from the diet typically resides in the human gut for several weeks from where it enters the brain of adults and foetuses, where it accumulates and is converted to inorganic mercury. MeHg is highly toxic and causes severe effects. These effects were seen following MeHg incidents in Iraq (contaminated grain) and Japan (contaminated seafood). In individuals who were exposed at the foetal stages, symptoms included mental retardation, cerebral palsy, deafness and blindness. People who were exposed to high mercury levels when they were adults underwent sensory and motor impairment.

Illness caused from low-level exposure

Recently, it has been suggested that low-dose exposure of the foetus to MeHg may lead to impaired performance, which appears when the individual reaches early childhood. According to Kjellstrom *et al.* (1989a, 1989b), Davidson *et al.* (1998), Johnson (1998), Levin (1998), Mahaffey (1998) and Myers (1998), young children exposed as foetuses perform badly in tests that measure attention, language, memory and fine-motor

function (called neurobiological tests). There is also evidence that exposure to MeHg can affect the cardiovascular system (blood pressure regulation, variable heart rate and heart disease). Exposure during the first trimester (three months) of pregnancy appears to be the critical period.

Studies on mercury intake in children

Two studies of children exposed to mercury via fish consumption have been undertaken: the Seychelles Islands in the Indian Ocean and the Faeroe Islands in the North Atlantic Ocean. Both countries have diets that are highly dependent on marine life.

The initial findings from the Seychelles study indicate that no significant mercury effect was found in children who had been exposed to a wide range of mercury levels during the foetal stages. The Seychellois usually eat fish twice a day with an average mercury content of 0.3 mg/kg. It should be noted, however, that the developmental tests used in the Seychelles study were less sensitive in detecting subtle cognitive and motor disturbances than tests used in the Faeroe study.

By contrast, the Faeroe study reported that children who were exposed prenatally to the highest mercury levels had slight abnormalities in development when tested at age seven. However, the biological significance of these findings remains unclear, as whale meat consumed by the Faeroe islanders contains other contaminants such as PCBs and has a higher mercury level than fish. Also, the Faeroe community often eats an entire whale in a short period of time, causing a spike in mercury levels that may affect the body differently than the lower consistent levels experienced in the Seychelles.

These initial results have been interpreted as indicating that the health effects of mercury on childhood development may be less severe than previously believed. A panel set up by the NAS found that children in the Seychelles study had no significant mercury effect. However, the NAS panel took a conservative course and recommended the retention of the EPA's reference dose (RfD) of 0.1 µg/kg body weight/day (see below).

Allowable intake – how much mercury is safe to take in from seafood consumption?

There are two recommended allowable intakes, based on the findings, on the one hand, of the US EPA and, on the other hand, by the Joint Expert Committee on Food Additives (JECFA) of FAO/WHO.

1. United States EPA Reference Dose

This is an estimate of the daily exposure of the human population (including sensitive subpopulations) that is likely to cause no adverse effects when experienced over a lifetime. The level is 0.1 µg/kg body weight/day (0.7 µg/kg body weight/week).

2. Joint FAO/WHO Expert Committee on Food Additives

This committee established a provisional tolerable weekly intake (pTWI) for MeHg of 5 µg/kg body weight/week.

There is a sevenfold difference between these recommended intakes, which has an important effect on how much fish a person is able to eat. The JECFA recommendation allows much more fish to be eaten.

Tables 20 and 21 give the weekly consumption of fish required to reach the recommended limits established by JECFA and the United States EPA. A range of mercury levels in fish is presented, which takes in species that do not accumulate much mercury (0.15 mg/kg fish flesh) and those that do (1.0 and 1.5 mg/kg fish flesh). Because the permitted intake of mercury varies according to the body mass, weight ranges are given for a typical 2 year old (13 kg), 12 year old (40 kg), adult female (60 kg) and adult male (70 kg).

As can be seen from Table 20, for non-predatory fish (average mercury level 0.15 mg/kg) an adult is able to consume almost 2.5 kg of fish per week before reaching the pTWI. Even if high mercury fish is consumed (1 mg/kg), an adult could consume 316–368 g/week without exceeding the limit.

When the EPA recommended levels are considered, by contrast, only very small quantities of mercury-containing species are able to be consumed. Using the EPA level of 0.1 µg/kg body weight/day (Table 21) adults would be able to consume only 44–52 g/week of those species with a mercury cootent of 1 mg/kg.

In summary, the hazard characterization indicates:

- a large discrepancy of allowable intake between regulatory bodies;
- inconclusive evidence that ingestion of mercury at the foetal stage is a hazard in childhood.

These factors will be integrated into the risk characterization matrix.

TABLE 20
Weekly consumption of seafood required for an individual of a given weight to reach the pTWI of 5 µg/kg body weight/week

Mercury level in seafood (mg/kg)	Weekly consumption (g)			
	13 kg	40 kg	60 kg	70 kg
0.15	456	1 404	2 105	2 456
0.5	137	421	632	737
1.0	68	211	316	368
1.5	46	140	211	246

TABLE 21
Weekly consumption of seafood required for an individual of a given weight to reach the EPA RfD of 0.1 µg/kg body weight/day

Mercury level in seafood (mg/kg)	Weekly consumption (g)			
	13 kg	40 kg	60 kg	70 kg
0.15	64	197	295	344
0.5	19	59	88	103
1.0	10	30	44	52
1.5	6	20	30	34

5.2.4 Exposure assessment

Your task

In this section you must estimate the quantity of mercury ingested per week by the target consumers – pregnant women in the first three months of pregnancy.

You will probably be able to find the quantity of high-mercury species landed in your country from annual catch statistics.

The next task is to determine the mercury content of the target species. The Health Department may have done some studies. Otherwise look for data from another country (see the Resources Bank).

Then you will need to convert it to an edible portion – 50 percent fillet yield is a good estimate.

Finally, you must make a decision on how frequently high-mercury species are eaten by pregnant women.

The following section is an example of how you make these calculations based on hypothetical data

Production of predatory species and number of servings

Annual catch statistics for landings of potentially high-mercury species, such as shark, billfish, swordfish and marlin, are presented in Table 22. Shark is the main component of high-mercury fish landed with lesser quantities of billfish, swordfish and marlin totalling 16 000 tonnes per annum. Since the edible portion for these species is around 50 percent of the gross weight, 8 000 tonnes are actually consumed, equivalent to 80 million servings of 100 g each serving.

Estimation of consumption pattern

Your country has a population of 20 million and there are consumption data showing that only 33 percent ever eat shark and gamefish. This means the 80 million servings are

TABLE 22
Production of species associated with elevated mercury levels

	Production (t)	Edible portion (t)	Servings (x10³)
Shark	12 000	6 000	60
Billfish	2 200	1 100	11
Swordfish	1 200	600	6
Marlin	600	300	3
Total	16 000	8 000	80

TABLE 23
Mercury levels in predatory fish

	Mean mercury (mg/kg)	
	Study 1	Study 2
Swordfish	1.9	2.4
Marlin	2.2	3.1
Shark	1.1	0.9
Billfish	1.5	0.9

eaten by 6.5 million of your countrymen and women, an average of one serving per month. The birth rate in your country is around 250 000 a year and, if it is assumed that the same proportion of pregnant women eat the high-mercury species as in the general population, then 33 percent of 250 000 (around 80 000) are at risk, or rather their foetuses are at risk. Since the critical period is the first three months, at any one time there are around 25 000 pregnant consumers eating fish that may have a high mercury content. These consumers eat one serving (100 g) once a month.

Studies on mercury levels in predaceous fish

The Health Department in your country has commissioned two studies of mercury levels in predaceous fish (summarized in Table 23 from which it can be seen that shark and billfish have mercury contents around 1 mg/kg with swordfish and marlin around 2–3 mg/kg).

In summary, based on the data contained in Tables 22 and 23, on an annual basis, pregnant women in their first trimester:

- number 25 000;
- consume around 300 000 servings of 100 g each per year;
- shark servings number 240 000 and contain 1 mg/kg of mercury, and gamefish servings number 60 000 and contain 2–3 mg/kg of mercury.

5.2.5 Risk characterization

The risk characterization requires inputs for exposure assessment, hazard characterization and links with epidemiology in your country.

Table 24 estimates the total intake of mercury by a 60 kg woman during the first three months (13 weeks) of her pregnancy.

TABLE 24
Total mercury intake during the first trimester (3 months) and comparison with intakes allowed by EPA and JECFA

	Shark	Gamefish
Number of servings in three months	2	1
Total quantity consumed (g)	200	100
Mercury content (mg/kg)	1	2-3
Mercury ingested (mg)	0.2	0.2–0.3
Total intake (shark + gamefish)	0.4–0.5 mg	-
Allowable intake for 60 kg woman over 13-week period	-	-
EPA RfD (0.7 µg/kg body weight/week)	0.5 mg	-
JECFA pTWI (5 µg/kg body weight/week)	3.9 mg	-

Based on monthly consumption of high-risk species, she will consume two servings (100 g) of shark and one of gamefish for a total mercury intake over the critical period of 0.4–0.5 mg mercury. This is the same as the limit allowed by EPA (0.5 mg) but well within that allowed by JECFA (3.9 mg) recommendations.

Table 25 is a template, which can be used for qualitative risk assessment, based on four factors: severity of the hazard, likelihood that the hazard will occur, exposure in the diet and linkage with illness.

Table 25 contains ratings that are somewhat subjective. For example:

- Severity of the hazard is rated low-medium for its effect on the foetus. Most countries follow the JECFA recommendations, rather than those of the EPA.

- Likelihood that predaceous fish are consumed reflects a medium rating since sharks are often a moderate component of the total finfish catch.
- Exposure in the diet is 0.4–0.5 mg over the critical period, which is within the EPA allowance and much lower than the JECFA allowance.

TABLE 25
Qualitative risk ranking of mercury in predaceous fish

	US EPA	JECFA
Severity of hazard	Low-medium	Low-medium
Likelihood of occurrence	Medium	Medium
Exposure in diet	Low	Very low
Linkage with illness	None	None
Risk ranking	Low	Low

- Linkage with illness in young people has not yet been conclusively made.

It is worth comparing the exposure in this assessment with exposure in the Minamata Bay incident, where finfish and shellfish harvested from the area contained mercury levels up to 29 mg/kg and were eaten at least daily by most people to give an estimated average MeHg intake of 0.3 mg/day (Coultate, 1992). For a woman weighing 60 kg this equates to 6 µg/kg body weight/day, or 42 µg/kg body weight/week, more than eight times the pTWI and 90 times the RfD.

5.2.6 Risk estimate

When all the inputs to Table 25 are considered, the risk ranking of consumption of predaceous fish by pregnant women is low.

5.2.7 Identification of critical data gaps

The assessment was constrained by time (only one month) and relied on "average" consumptions. Fish consumption patterns, as opposed to averages, are needed to assess the risk of mercury poisoning, particularly for pregnant women and their foetuses. Obtaining data on groups with above average fish consumption would enhance the assessment. If residents in coastal communities or people who work aboard vessels that fish for marlin and swordfish become pregnant they are, as a group, at a greater risk.

5.2.8 Risk management and communication

Public comment

The risk managers submit your assessment for public comment from stakeholders.
The most important replies are:

1. *The seafood association denies completely that mercury has any role in illness, other than the Minimata incident, where the exposure was extremely high (daily or twice-daily consumption of products extremely high in mercury). They also suggest that limiting consumption of seafoods will have negative health aspects given the unequivocal evidence linking polyunsaturated fatty acids with reduced heart disease.*
2. *The Consumers' Association considers the assessment underestimates the risk to the foetus and that the rating should be "high". Even though evidence is not yet conclusive, the association considers "the jury is still out" and that the assessment should be more conservative. They cite the NAS judgement in favour of the more EPA level as evidence that the assessment should be more conservative.*

Cont.

Risk management

The risk managers make the following observations and decisions:

- *Given the consumption patterns, the risk is borne by around 25 000 pregnant consumers at any one time.*
- *Warnings will be carried in every hospital and every doctor's surgery that consumption of shark and gamefish may lead to motor impairment in the child and that these species should not be consumed more than once a week during the first four months of pregnancy.*
- *These warnings are based on levels recommended by JECFA.*
- *Regulatory bodies in several countries, e.g. United States (FDA) and Australasia (Food Standards Australia New Zealand) have decided to follow JECFA recommendations.*
- *The known benefits of seafood consumption outweigh the possible negatives associated with (as yet unproven) motor impairment.*
- *There are already size limits for sharks, which partially reduce the hazard.*
- *The topic will be kept under constant review and any new evidence will be assessed.*

5.3 HOW TO PERFORM A SEMI-QUANTITATIVE RISK ASSESSMENT: CIGUATERA FISH POISONING

The situation

Your country is composed of a number of atolls in the South Pacific, which have valuable reef fish. A tourist industry has sprung up following the construction of an airstrip capable of taking medium-sized jets. There is also the possibility of exporting reef fish twice a week by air to New Zealand and Australia, where there are large populations of Pacific islanders.

However, there is a large outbreak of ciguatera fish poisoning involving both local people and tourists.

The chief minister is asked by New Zealand authorities to undertake a risk assessment of consumption of reef fish.

You are given the task of doing the risk assessment within a time frame of one month. This allows you time to gather data only from your health department on cases reported, plus data on consumption patterns in your country and in New Zealand.

Your risk assessment will be used by the risk managers, who may require you to do follow-up work on further questions that may emerge from the consultation process with stakeholders.

Your resources include:

- *Information on ciguatera from the Resource Bank (Hazard Identification, Hazard Characterization), which can be used as start-up material.*
- *Risk Ranger for making semi-quantitative risk estimates.*

5.3.1 Purpose of the assessment

The purpose of the assessment is to estimate the risk of CFP from fish caught from the reef systems around your atoll nation. The assessment must examine consumption of reef fish by two populations:

- the local population, including tourists;
- consumption in New Zealand, where a market exists, mainly for expatriates from the Pacific islands.

Because there has been a large outbreak of CFP, you have only one month in which to complete the assessment and report to the risk managers. This is a severe time constraint, which allows you only to do desk-top work; there will be no time to do any laboratory testing for ciguatera in reef fish.

5.3.2 Hazard identification

The illness

It is reported that up to 50 000 people may experience CFP each year, after eating fish caught in subtropical and tropical waters, often near reefs. The fish become toxic because they accumulate naturally occurring toxins produced by marine algae (predominantly *Gambierdiscus toxicus*), which are part of the food chain.

Outbreaks of CFP

Ciguatera is the most common illness caused by consumption of finfish. It is endemic in the Caribbean and in subtropical Indo-Pacific regions. In countries that import reef fish and/or have reef systems, such as the United States, Australia and Canada, CFP is a major cause of seafood-borne illness (Table 26). The largest and most damaging outbreak occurred in Madagascar in 1994 when 500 people were poisoned and 98 died following consumption of shark (*Carcharhinus* sp.).

While it is likely that a large proportion of cases go unreported, CFP rates in some regions are still high. In the Caribbean, Ruff and Lewis (1994) report rates of 30 cases/ 10 000 population/annum (Guadeloupe) and 73 cases/10 000 population/annum (US Virgin Islands). In the South Pacific, rates are around 100 cases/10 000 population/ annum (Kiribati) and 300 cases/10 000 population/annum (Tuvalu).

Fish species that produce CFP

It is thought that, worldwide, less than 100 species produce CFP, the most predominant of which are presented in Table 27. Both common and Latin names are included.

It is important to use correct names because sometimes a marketing name can hide the fact that the species is potentially ciguatoxic. For example, in Australia in 2000 an outbreak of CFP occurred from "Queenfish" which, while not considered a potentially ciguatoxic species by some, was actually *Scomberoides commersonnianus*, a species regularly implicated in ciguatera poisonings.

In the Indian Ocean (Réunion Island), *Plectropomus* spp. (coral trout) was responsible for more than 50 percent of all outbreaks (Quod and Turqet, 1996).

In the United States, ciguatera is most often caused by groupers (*Epinephalus* spp.) in Florida and amberjacks (*Seriola* spp) in Hawaii (Sours and Smith, 1980).

TABLE 26
Outbreaks of CFP in the United States, Canada and Australia

Country	Period	Number of outbreaks	Percentage of all seafood outbreaks	Total ill	References
USA	1990–2000	75	32	328	Smith de Waal *et al.* (2000)
Australia	1990–2000	10	31	616	Sumner and Ross (2002)
Canada	1983–1997	15	Not known	53	Todd (1995)

TABLE 27
Fish species most commonly associated with ciguatera outbreaks

Latin name	Australian common name
Scomberomorus commerson	Spanish mackerel
Scomberomorus spp.	Mackerels
Sphyraena jello	Barracuda
Plectropomus spp.	Coral trout
Epinephelus fuscoguttatas	Flowery cod and other epinephalids
Lutjanus sebae	Red emperor
Lutjanus bohar	Red bass
Scomberoides commersonnianus	Giant dart
Lethrinus nebulosa	Yellow sweetlip
Seriola lalande	Yellowtail kingfish and other seriolids
Caranx sp.	Trevally
Cephalopholis miniatus	Coral cod
Chelinus trilobatus	Maori wrasse

In Australia, mackerels have been responsible for around 75 percent of all cases and outbreaks, with barracuda, coral trout, lutjanids and epinephalids (groupers) bringing the total to >90 percent.

In Fiji, species most commonly connected with ciguatera are similar to those in Australia: *Lutjanus bohar* (Red sea bass), *Sphyraena* (Barracuda), *Epinephelus* (Flowery cod), *Lethrinus miniatus* (Long-nosed snapper), *Plectorhynachus* (Grouper). Moray eel, the most toxic of fish is not usually eaten, except in some Pacific countries, where it is sometimes eaten as a delicacy.

5.3.3 Hazard characterization

Your task

You need to investigate the symptoms of CFP so that you can make the correct choice in Questions 1 and 2 of Risk Ranger – degree of severity of the illness and proportion of the population that is affected.

There is a review by Lehane and Lewis (2000), which provides information on all aspects of CFP. It is especially useful because it has been written in Risk Assessment format. It is contained in the Resources Bank.

The early stages of the illness (3–12 hours after ingestion) are gastrointestinal (nausea, vomiting, diarrhoea and stomach cramps). Between 12–18 hours after consumption, neurological symptoms begin, including numbness of the lips and extremities, muscular paralysis, convulsions, memory loss, headache. Some victims undergo psychological disturbances such as anxiety and depression for some months while others undergo cardiovascular symptoms.

Ciguatera poisoning is usually self-limiting and signs of poisoning often subside within several days from onset. However, in severe cases the neurological symptoms persist from weeks to months and, in rare cases, for several years. Sometimes, patients experience recurrence of neurological symptoms months to years after recovery. There is usually a low incidence of death resulting from respiratory and cardiovascular failure though in one outbreak in Madagascar, of the 500 affected, 98 died (Habermehl *et al.*, 1994).

Clinical testing procedures are not available for the diagnosis of ciguatera in humans, which is based entirely on symptoms and recent dietary history. The disease has only recently become known to the general medical community and may be under-reported because of the generally non-fatal nature and short duration of the disease.

All humans are believed to be susceptible to ciguatera toxins. Populations in tropical/subtropical regions are most likely to be affected because of the relatively higher frequency of exposure to toxic fishes. Repeated ciguatoxin exposures are associated with more severe illness (Glaziou and Martin, 1993; Katz, Terrellperica and Sasaki, 1993).

Infectious Dose/Dose Response

Ciguatoxins are lipid-soluble toxins that remain toxic after cooking. Ciguatoxin (CTX-1) is usually the major toxin (on the basis of both quantity and total toxicity) present in fish and typically contributes ~90 percent of total lethality. On the basis of available outbreak data, Lehane (1999) estimated the minimum toxic dose to be ~50/ng in an adult of 50 kg weight (~1ng/kg body weight). However, in one well-documented incident, six United States soldiers became ill after eating fish containing approximately 20ng ciguatoxin/g flesh. They all presented with nausea, vomiting, watery diarrhoea and abdominal cramps 5–8 h after consumption and some also had numbness in the extremities or around the mouth, abnormally slow heartbeat (bradycardia) and paresthesia – tingling of the scalp (Poli *et al.*, 1997).

Some studies indicate that increased toxin dose leads to increased severity of cardiovascular effects in animals and humans (Katz, Terrellperica and Sasaki, 1993). However, Arcilaherrera *et al.* (1998) found no association between the amount of toxic fish ingested and the severity and duration of the symptoms. It is well recognized that, with repeated exposure, more severe and prolonged symptoms occur.

Inputs for Risk Ranger

Question 1: Select MILD HAZARD – sometimes requires medical attention
Question 2: Select GENERAL – all members of the population

5.3.4 Exposure assessment

Your task

In this section you must estimate mass of potentially ciguatoxic fish consumed in your Pacific island nation and in New Zealand, the importing country.

You will find the quantity of potentially ciguatoxic species landed in your country from annual catch statistics.

Then you will need to convert it to edible portion – 50 percent fillet yield is a good estimate for all species except mackerels, which give a filleting yield around 70 percent.

Finally, you must estimate number of servings and consumption patterns in your country and in New Zealand.

An example follows of how you make these calculations based on some hypothetical data.

Calculate volume of potentially toxic fish landed

Table 28 presents landings, yield of edible portion and number of servings of potentially ciguatoxic species in the Pacific island nation.

All species have an assumed 50 percent yield of edible portion with the exception of mackerels which have 70 percent yield. From Table 28 it can be seen that around 600 tonnes of potentially ciguatoxic species are available for consumption, giving around six million servings.

TABLE 28
Production (t) of potentially ciguatoxic species

Species	Landed volume (t)	Edible mass (t)	Servings ($x10^6$)
Trevally	100	50	0.5
Yellowtail kingfish	100	50	0.5
Mackerels	600	400	4
Groupers	100	50	0.5
Red emperor	100	50	0.5
Total	1 000	600	6

Consumption pattern and number of servings

Of the 600 tonnes available for consumption, 100 tonnes are consumed locally and 500 tonnes exported to New Zealand. Locally, one million servings are consumed by all of the population, which comprises 10 000 people. Thus, on average, every member of the population consumes the target species twice a week, on average. Fish is eaten almost every day, and tuna and dried flying fish (neither of which has a history of ciguatoxin production) are major components of the diet.

The 500 tonnes of exported species yields five million servings, which are consumed by about 25 percent of the total population of four million. Thus, on average, each of the one million consumers eats a serving of potentially ciguatoxic fish five times each year.

Inputs to Risk Ranger for probability of consuming the target species

	Local consumers	NZ consumers
Question 3: Frequency of consumption	Weekly	Few times a year
Question 4: Proportion consuming	All (100%)	Some (25%)
Question 5: Population	10 000	4 000 000

Contamination levels in servings

Unfortunately, all literature searches are negative with no data available for prevalence of ciguatoxin in reef fish from Pacific atolls or islands. Thus it is assumed that one in 1 000 fish will have a ciguatoxin level that can cause illness.

Inputs to Risk Ranger for contamination level through processing to consumption

Question 6: Probability of contamination	Rare (1 in 1 000 servings)
Question 7: Effect of processing	No effect on the hazard
Question 8: Recontamination	No recontamination
Question 9: Effect of post-process handling	No effect on the hazard
Question 10: Post-process increase to illness	None
Question 11: Effect of meal preparation	No effect on hazard

5.3.5 Risk characterization

In characterizing the risk of contracting CFP, two population categories are considered:

- local consumers, for whom reef fish are a major component in the diet;
- consumers in the importing country who rarely eat imported reef fish. In fact, the majority of consumers may be expatriate islanders.

Table 29 lists the inputs that are needed for a semi-quantitative risk characterization for the two at-risk groups. The inputs are identical except for the exposure of the two populations. The local population is exposed on a regular basis. Consumers in the importing country are exposed less frequently but there are more servings.

When information is inserted in Table 29 two estimates of risk are obtained:

- risk ranking;
- predicted illnesses in the target consuming populations.

TABLE 29

Semi-quantitative risk characterization of consumption of ciguatoxic fish species

Risk criteria	Local population	Consumers in importing country
Dose and severity		
Hazard severity	Mild – sometimes requires medical attention	Mild – sometimes requires medical attention
Susceptibility	General – all population	General – all population
Probability of exposure		
Frequency of consumption	Weekly	Few times a year
Proportion consuming	All	Some (25%)
Size of population	10 000	4 million
Probability of contamination		
Probability of raw product contaminated	0.01% ciguatoxic	0.01% ciguatoxic
Effect of processing	Does not eliminate the hazard	Does not eliminate the hazard
Possibility of recontamination	None	None
Post-process control	Not relevant	Not relevant
Increase to infective dose	None	None
Further cooking before eating	Not effective in reducing hazard	Not effective in reducing hazard
Total predicted illnesses per annum in selected population	520	3 000
Risk ranking (0-100)*	61	51

* Note that an increment of "six" is equivalent to a tenfold change in risk

In the above, risk characterization processing has no effect on ciguatoxin, so no matter if the fish is chilled, frozen or dried, the level of ciguatoxin will not change. Storage prior to consumption similarly does not affect the level of toxin and neither

does the type of cooking. The level of ciguatoxin at the point of capture is identical with that at consumption.

5.3.6 Risk estimate

Based on the above assumptions, the Risk Ranking for fish consumed locally is 61, reflecting the greatly increased exposure to the hazard, with 520 illnesses predicted per annum in the total population of 10 000 islanders.

In the importing country, the Risk Ranking is 51 with 3 000 annual illnesses predicted in the New Zealand population of 4 million.

5.3.7 Reality check

Since an assumption was made of a key component in exposure to the hazard – prevalence of fish that have a ciguatoxic dose – it is useful to do a reality check to see whether the estimates of illness are of the correct order of magnitude. By expressing cases of CFP/ 10 000 population we can compare the prevalence in the present assessment with those published for island communities. Lehane and Lewis (2000) quote 100 cases/10 000 population per annum in South Pacific island nations. The same authors also consider under-reporting to be common and the present assessment, 520 cases/10 000 population, is therefore of the same magnitude as that quoted by Lehane and Lewis.

5.3.8 Data gaps in the present assessment

A major lack of information surrounds prevalence of ciguatoxic fish landed. If possible, some work should be done using test kits. Serological test kits for the detection of ciguatoxin are now available commercially, one of which is Cigua-Check Fish Poison Test Kit Oceanit Test Systems, Inc., http://www.cigua.com. There are other kits available.

5.3.9 Risk management and communication issues

Public comment on the risk assessment

Your assessment is submitted by the risk managers to public comment and, one week later, a meeting is held at which a number of issues emerge:

- *The Health Department says your estimate of 520 cases per annum is about right, their records indicate they treat about ten people a week for ciguatera-like symptoms. They sometimes administer mannitol-based solutions intravenously to assist in treating symptoms. They believe as many as 10–20 percent of the population may suffer CFP symptoms to some degree each year.*
- *The Tourism Department provides news clippings from New Zealand and Australian newspapers reporting that more than 20 people from the same tour group had CFP symptoms. They also report a fall in bookings following the problem.*
- *The fishermen's association states that there is no evidence that CFP occurs and that the alleged symptoms have never been followed up to confirm the cause. They say their livelihood cannot be taken away without firm evidence.*

Risk management – round one

The risk managers who represent health, political, legal and commercial interests in your island nation submit two issues for your further assessment, to be completed in two weeks:

1. *Examine all data from the Health Department and try to confirm whether CFP does occur at the rate suggested by the risk estimates.*
2. *Assess the fishermen's association claim that CFP is not the cause of illnesses.*

Health Department data and the fishermen's association claims

Health Department records include name, age, address, date of illness, type of fish consumed and symptoms for each person. Staff is very knowledgeable on symptoms of CFP. Health Department data are summarized in Table 30.

Health Department data reveal a number of key facts:

- In the last two years there have been almost 1 200 reported cases of illness, the symptoms of which are consistent with CFP.
- Most illnesses are family outbreaks involving most or all members.
- The younger members are often more badly affected and need treatment with mannitol.
- Almost invariably, the family has consumed reef fish just prior to the illness.
- Most cases are in the first half of each year, during and after the cyclone season, when the reef is always damaged. Reef damage is often a precursor to colonization by dinoflagellates and build-up of ciguatera fish poison in reef fish.

TABLE 30
Health Departments records for CFP cases 2000–2001

Date	Probable cases of CFP*	Suspected cases of CFP**
Jan–Mar 2000	44	108
April–June 2000	112	323
July–Sept 2000	6	21
Oct–Dec 2000	4	15
Jan–Mar 2001	34	79
April–June 2001	69	287
July–Sept 2001	18	43
Oct–Dec 2001	4	9
Total	291	885

*Probable cases have typical CFP symptoms which respond to mannitol treatment.
** Suspected cases of symptoms that do not require mannitol treatment

Risk communication

Taken together, these facts point firmly to CFP as the cause of the problems that your country is encountering.

When the data are presented to the fishermen's association they are received more sympathetically and the association asks what can be done about the problem.

There is now acceptance by all parties to work together to promote tourism and exports and to eradicate the almost endemic CFP among your local population.

Risk management

The risk managers take two courses of action:

- *Not taking reef fish after the cyclone season or when reef damage occurs. The Fisheries Department will police this;*
- *Importing finfish from New Zealand for the tourist industry.*

The two strategies will virtually eliminate risk because there will be no exposure to the hazard. However, intuition tells you that the reefs will still be fished and that CFP will still occur in the local population.

As well, you still have no data on the prevalence of ciguatoxin in reef fish.

You persuade the fishermen's association to lobby the government for funds to buy diagnostic kits for determining presence of ciguatoxin and its approximate concentration.

Over the next two years you will test reef fish as they are landed at the fishermen's cooperative and try to pinpoint ciguatera "hot spots". If this is related to reef damage and any other likely factors, you may be able to reassess the banning of reef fishing for such a significant part of the year.

5.4 HOW TO PERFORM A SEMI-QUANTITATIVE RISK ASSESSMENT: HISTAMINE FISH POISONING

The situation

Your country exports chilled tuna by air.

Almost all the catch goes to a single importing country.

Recently, your Minister of Fisheries learned that there have been cases of HFP in one importing country, and the product from your country is under suspicion.

As a result, the authorities in the importing country are insisting that you carry out a risk assessment of histamine production in tuna produced in your country.

Fish is caught on lines from small, twin-hull, open boats which carry no refrigeration. More than 200 small boats operate, fishing overnight trips.

Your country has five processing plants which operate HACCP plans and there are daily flights which transport chilled product to the importing country.

You have a three-month time frame in which to carry out the assessment and it may be necessary to conduct a second risk assessment to evaluate any industry changes following the first assessment.

5.4.1 Purpose of the assessment

The purpose of the assessment is to estimate the risk of HFP from fish caught and processed in your country.

Risk Ranking will form a semi-quantitative assessment.

You have three months in which to complete your assessment so there are time constraints that will prevent you doing laboratory work. You can, however, do temperature:time studies and use the predictive microbiology approach.

5.4.2 Hazard identification

Traditionally, HFP has been associated with consumption of scombroid fish from the families *Scombridae* and *Scomberosocidae* (mackerels, tunas and kingfish). More recently, non-scombroid fish have also caused identical symptoms and so "Scombroid poisoning" may not be the best description – hence the use of HFP to describe the symptoms (below).

The illness

The illness has a range of symptoms (Table 31).

Questions have been asked whether histamine is the sole cause of the illness. Lehane and Olley (1999) and Clifford and Walker (1992) both consider compounds other than histamine are involved. However, it is probable that histamine is the main hazard because:

- Symptoms are typical allergic reactions caused by histamine – often within a few minutes of consuming the affected food item.
- Antihistamine therapy works relatively quickly (usually less than eight hours).
- High levels of histamine are often found in seafood that has caused the reaction.

TABLE 31

Symptoms of scombroid fish poisoning

Type	Symptoms
Cardiovascular	Flushing, urticaria (nettle-rash), hypotension (low blood pressure) and headache
Gastrointestinal	Abdominal cramps, diarrhoea, vomiting
Neurological	Pain and itching associated with the rash

TABLE 32
Outbreaks of HFP in United States, United Kingdom and Australia

Country	Period	Number of outbreaks	Percentage of all seafood outbreaks	Total ill	Reference
USA	1990–2000	103	43	680	Smith de Waal et al. (2000)
UK	1992–1999	47	32	-	Scoging (1998)
Australia	1990–2000	10	31	28	Sumner and Ross (2002)

Outbreaks of HFP

Histamine poisoning occurs throughout the world and is perhaps the most common form of toxicity caused by the ingestion of fish. However, reliable statistics about its incidence do not exist because the poisoning incidents are often unreported because of the mild nature of the illness, lack of adequate systems for reporting food-borne diseases or ignorance by medical personnel who misdiagnose histamine poisoning as a food allergy (Taylor, 1986; Lehane and Olley, 2000). Japan, the United States and the United Kingdom are the countries with the highest number of reported incidents, although this possibly reflects better reporting systems. Frequent incidents have been reported elsewhere in Europe, Asia, Africa, Canada, New Zealand and Australia (Ababouch *et al.*, 1991; Lehane and Olley, 2000). Table 32 shows, however, that the number of people affected in outbreaks is usually not great.

Fish species most commonly implicated

Species in the families *Scombridae* and *Scomberosocidae* that have been implicated in outbreaks of HFP include: mackerel (*Scomber* spp.), tuna (*Thunnus* spp.), saury (*Cololabis saira*) and bonito (*Sarda* spp.). Non-scombroid fish include: mahi-mahi (*Coryphaena* spp), sardines (*Sardinella* spp.), pilchards (*Sardina pilchardus*), marlin (*Makaira* spp.), bluefish (*Pomatomus* spp.), sockeye salmon (*Oncorhynchus nerka*), yellowtail (*Seriola lalandii*) and Australian salmon (*Arripis trutta*).

Formation of biogenic amines

The biogenic amines are produced in fish tissues by bacteria in the family *Enterobacteriaceae*, e.g. *Morganella*, *Klebsiella* and *Hafnia*. The bacteria produce decarboxylases that convert amino acids in the fish to biogenic amines:

Histidine → Histamine
Ornithine → Putrescine
Lysine → Cadaverine

The bacteria are naturally occurring in the gills and intestines of the fish and may be spread to other sites in the fish during handling. The nape of the neck appears to be more heavily contaminated than other parts of the fish, possibly due to the gilling and gutting process.

Once histidine decarboxylase has been produced, it may continue to produce histamine, even though bacterial growth has been prevented by chilling to 4 °C. Ababouch *et al.* (1991) showed that histamine production can increase even in ice storage.

5.4.3 Hazard characterization

Your task

You need to investigate the symptoms of HFP so that you can make the correct choice in Questions 1 and 2 of Risk Ranger – degree of severity of the illness and proportion of the population which is affected.

There is a review by Lehane and Olley (2000) which provides information on all aspects of HFP. It is especially useful because it is written in Risk Assessment format.

There is also a large review by the United States Institute of Food Technologists (IFT) on biogenic amines

HFP is caused by the ingestion of foods that contain high levels of histamine and possibly other amines and compounds. Neither cooking, canning, nor freezing reduces the toxic effect (Shalaby, 1996; FDA, 1999).

Infectious dose/dose response

The threshold toxic dose for histamine is not precisely known and scombroid poisoning has occurred at histamine levels as low as 50 mg/kg. However, most incidents involve fish with histamine levels of 200 mg/kg and over (Fletcher, Summers and van Veghel, 1998). The variation may reflect the role that biogenic amines other than histamine play in scombroid poisoning.

Simidu and Hibiki (1955) estimated the threshold toxic dose for histamine in fish at approximately 60 mg. Shalaby (1996) reviewed the oral toxicity to humans of histamine and other biogenic amines in foods. He considered that histamine-induced poisoning is, in general, slight at ≤40 mg, moderate at >40 mg and severe at >100 mg. Based on an analysis of recent poisoning episodes, Shalaby (1996) suggested the following guideline levels for histamine content of fish:

- <5 mg/100 g (safe for consumption)
- 5–20 mg/100 g (possibly toxic)
- 20–100 mg/100 g (probably toxic)
- >100 mg/100 g (toxic and unsafe for human consumption)

It has also been suggested that neither histamine nor biogenic amines are responsible for HFP (Clifford and Walker, 1992). In the period 1976–86, over half the cases in the United Kingdom were associated with histamine levels of less than 50 mg/kg, a level not normally considered to be toxic. Further, volunteers who were fed mackerel with 6 000 mg/kg histamine reported only mild tingling around the mouth. Taken together these two facts led Clifford and Walker (1992) to suggest that the role of dietary histamine in scombroid poisoning may be slight. The same authors also suggest that Saxitoxins (Paralytic Shellfish Poison) may be involved in scombroid poisoning symptoms associated with salmon. Lehane and Olley (1999) speculate that urocanic acid may be the missing factor ("scombroid toxin") in histamine fish poisoning.

However, histamine levels are still used by regulatory bodies. In the United Kingdom, guidelines for histamine levels in fish (Scoging, 1998) are:

- Safe <10 mg/100 g
- Potentially toxic 10–50 mg/100 g
- Probably toxic 50–100 mg/100 g
- Toxic >100 mg/100 g

The United States FDA guidelines, established for tuna, mahi-mahi and related fish, specify 50 mg/100 g as the toxicity level, and 5mg/100 g as the defect action level because histamine is not uniformly distributed in fish that has undergone temperature abuse. Therefore, if 5 mg/100 g is found in one section, there is a possibility that other units may exceed 50 mg/100 g (FDA, 2001a). FDA requires the use of the AOAC fluorometric method (Rogers and Staruszkiewicz, 1997).

The European Union (EU, 1991, 1995) requires that nine samples be taken from each batch of fish species of the following families: *Scombridae, Clupeidae, Engraulidae* and *Coryphaenidae*. These samples must fulfil the following requirements:

- Mean value of all samples must not exceed 10 mg/100 g
- Two samples may be >10 mg/100 but <20 mg/100
- No sample may exceed 20 mg/100

However, fish belonging to these families that have undergone enzyme ripening in brine may have higher histamine levels, but not more than twice the above values. Examinations must be carried out in accordance with reliable, scientifically recognized methods, such as high-performance liquid chromatography (EU, 1991; 1995).

In Australia and New Zealand, the level of histamine in a composite sample of fish or fish products, other than crustaceans and molluscs, must not exceed 20 mg/10 g. A composite sample is a "sample taken from each lot, comprising five portions of equal mass from five representative samples".

Susceptible populations

It is widely believed that all humans are susceptible to scombroid poisoning (FDA, 1999) though symptoms can be severe for the elderly (FDA, 1999) and for those taking medications such as isoniazid, a potent histaminase inhibitor (Morinaga *et al.*, 1997).

Inputs for Risk Ranger

Question 1: Disease is mild, requiring medical attention only rarely

Question 2: General population is at risk with no susceptible population categories

5.4.4 Exposure assessment

Your task

In this section you must identify, from annual catch statistics, the tonnage of fish that are able to produce histamine.

Then you will need to convert the landed amount to edible portion – 80 percent fillet yield is a good estimate.

Finally, you must estimate number of servings and consumption patterns in the country to which you export species capable of producing histamine.

Following is an example of how you make these calculations based on hypothetical data.

Volumes of species known to produce histamine

Volumes of each species exported from your country and that may cause HFP are presented in Table 33. The catch data were gained from analysing receival dockets at each processing plant for one year. Small boats land 6 000 tonnes, which is processed and exported chilled to one country.

Edible weight and number of servings

After processing, the actual weight exported is 4 800 tonnes and, assuming that 100 g is a typical serve, there are 48 million annual servings exported.

Consumption patterns in consumer country

Market data tells you that a few (5 percent) people in the importing country ever eat chilled tuna. The population of the importing country is 270 million, which means that 48 million servings of tuna are eaten by 13 million consumers. This means that each consumer has an average of four servings each year.

TABLE 33
Species and volumes (tonnes) exported

Common name	Latin name	Volume (t)	Edible portion (t)	Servings (10^6)
Yellowtail kingfish	*Seriola* spp.	1 000	800	8
Tunas	*Thunnus* spp.	4 000	3 200	32
Mahi-mahi	*Coryphaena* spp.	1 000	800	8
Total		6 000	4 800	48

Inputs to Risk Ranger for probability of consuming fish that may have histamine	
Question 3: Frequency of consumption	Few times a year
Question 4: Proportion consuming	Very few (5 percent)
Question 5: Population	250 000 000

Contamination levels in servings

Your task

In this section you estimate the number of servings capable of causing HFP:

- *Estimate histamine levels of fish on board the boats.*
- *Estimate increase in histamine levels during processing and transport.*
- *Assess potential for product to reach toxic levels during marketing and retailing.*
- *Determine effect of meal preparation on toxin levels.*

This is difficult because of time constraints. If you had several months you could do a survey of measuring histamine levels of fish on boats and then through the processing and transporting chain.

Or, you could survey levels of histamine-producing bacteria at every stage of catching, processing and transporting.

These are large, time-consuming and expensive surveys. One day you may wish to do them but there is another way of estimating histamine levels – by using predictive microbiology.

Predictive microbiology is especially suitable for estimatmg histamine production because, if you know the temperature of product on the boat, and in the processing and transporting chain, you can predict the amount of bacterial growth.

This is done using data on growth rates of histamine-producing bacteria at key temperatures and integrating them with the temperature:time parameters of product.

You need to generate temperature:time data from the moment the fish are landed on the boat, then during processing and transport, to the moment they are placed in their final storage medium in the country of destination.

This is done using small data loggers which record temperatures at intervals. On board the vessel, loggers are placed in the gills and the gut.

Back on land, the data loggers are downloaded and a temperature:time profile generated (see Figures 2 and 3)

Figure 2 summarizes the process by which tuna and other species capable of accumulating histamine are caught, processed and transported to market.

The task is to estimate levels of histamine throughout the process and this is done by examining each stage of the process. Histamine, itself, will not be estimated in this risk assessment. Instead, the growth of histamine-producing bacteria will be predicted using temperature-time measurements of product, coupled with growth rates of histamine-producing bacteria.

Contamination of fish on the boats

Histamine-producing bacteria such as *Morganella*, *Klebsiella* and *Hafnia* convert amino acids in the fish to biogenic amines like histamine. These bacteria occur naturally in the gills and intestines of the fish and are spread to other sites in the fish during handling.

Factors which affect build up of histamine and other biogenic amines in seafoods include:

- Free histidine levels in fish muscle.
- Location of histamine-producing bacteria: On board the vessel, knife work

FIGURE 2
Process model for catching and processing tuna for chilled air freight from large and small boats

Catching and landing
Killing and spiking
Bleeding
Gilling and gutting

Small boat handling
Fish stored in bottom of boat
Covered by wet sacking
Unloading

Active chilling
Fish held in salt water:ice slurry until processed

Processing
Grading
Weighing
Process to customer specifications
Pack in carton
Add ice gel packs
Close and strap carton
Label with destination
Place in chill storage until load out to aircraft

Air journey
Airport handling
Refrigerated storage

Retail/food service handling

and removing the bloodline will spread histamine-producing bacteria to these sites. These are termed "sites of microbiological concern" because it is here that histamine is produced.

- Temperature at which product is stored: If temperature at the sites of microbiological concern is controlled, histamine production is controlled.

It is important to know the levels of histamine-producing bacteria on tuna after on-board handling. In a study on Pacific mackerel (*Scomber japonicus*), Kim *et al.* (2001) found very low levels of histamine-producers (<10 cm^2 on the gills and <10 g in

the gut), and these organisms produced histamine only slowly at 4 °C and not at all at 0°C. This finding is typical of many others, which indicate that histamine formation is controlled by temperatures at 4 °C or below.

At abusive temperatures (20–30 °C), however, histamine is formed quickly and, importantly, the enzyme histidine decarboxylase is produced and excreted from the bacterial cells onto the fish muscle. The enzyme is active at 0°C as indicated by Ababouch *et al.* (1991) who showed that on sardine held at ambient temperature (approx 25 °C) for 24 hours, histamine continued to be produced even after the fish had been placed in ice storage for a week. Klausen and Huss (1987) similarly showed that after mackerel had been held at 10 °C for two days, histamine continued to increase even when the fish were stored in ice.

So it is vital to quickly cool the sites of microbiological concern on fish to prevent formation of histidine decarboxylase. On ungutted fish these are the skin, gills and gut contents. However, in the system under review, there is no cooling for up to 10 hours.

Temperature: time parameters for fish on boats

Typically, boats fish overnight in a trip of up to 12 hours. Travel to the fishing grounds takes about 3 hours, lines are set and the first fish are landed about 4 hours into the trip. Storage is at ambient temperature (25–28 °C) until unloaded at the processing plant – the first-caught fish have been already stored for up to 10 hours. As fish are caught throughout the trip they are added to the catch in the bottom of the boat and kept moist with wet sacking. Fish from the last set are landed about 4 hours before the vessel arrives home.

A typical temperature:time curve for product at the site of microbiological concern (the gut) is presented in Figure 3 from which it can be seen that the first-caught fish are kept at ambient temperatures for up to 10 hours, prior to rapid chilling in the processing plant.

For inputs to Risk Ranger, only assumptions can be made on the rate at which servings are contaminated.

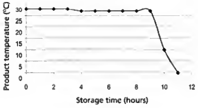
Assumption 1: That all (100 percent) tuna landed contain histamine-producing bacteria in the gills and gut, and on the skin (see Kim *et al.*, 2001).

Assumption 2: That these bacteria are present at 10/cm² of gill surface or 10/g of gut contents (see Kim *et al.*, 2001).

Assumption 3: That the contamination is confined to fish surfaces, and the deep muscle tissues remain sterile.

Assumption 4: That a 30 kg tuna will give around 250 servings of 100 g of which 1 percent (servings with external tissues on which histamine has been

FIGURE 3
Fish temperatures (°C) on boats



Although only short (overnight) trips are made, the first-caught fish is kept at ambient temperature of 25–28 °C for up to 10 hours. Once landed, fish are processed (gilled and gutted) and placed in ice:water slurry.

produced) will be contaminated with sufficient histamine to cause illness.

Assumption 5: That during processing, there is a recontamination rate because the numbers of histamine-producers will have multiplied.

Assumption 6: That in fish held at 25–28 °C, histamine-producers have a doubling time of 60 minutes without any delay due to lag phase (typical doubling time for mesophilic *Enterobacteriaceae*).

Over 10 hours storage on the boat, therefore, will cause histamine producers to undergo nine doublings, an increase of 1 000 times (three log scales) over the original assumed level of 10/g or cm^2 to reach a level of 10 000/cm^2 at fish surfaces or 10 000/g in the gut. Not only is this a high level of contamination, which will be spread during on-land processing, but significant quantities of histamine decarboxylase will have been secreted onto the fish, and this will continue to produce histamine during transport and marketing.

Inputs to Risk Ranger for contamination with histamine-producing bacteria on fish at time of landing aboard the vessel

Question 6: Frequency of contamination	percent
Question 7: Effect of process	Holding on the boat has no effect on the prevalence of contamination
Question 8: Potential for recontamination	10 percent

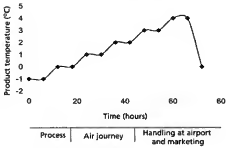
Temperature: time parameters of product in process, transport and retail/ food service

At the processing plant, fish are gilled and gutted, then stored in ice until packed for air transport to the consumer country. The HACCP contains details of how the exporter maintains product temperature throughout the 24–36 hour journey. By inserting data loggers in product, a typical temperature profile of tuna during processing, transport and handling in the importing country is shown in Figure 4.

As indicated in Figure 4, product temperature is controlled during all land-based activities although histamine can be expected to increase because of histidine decarboxylase activity.

Again the inputs to Risk Ranger must be assumed.

FIGURE 4
Temperature (°C) and time (hours) during transport to customer



Product temperatures gradually rise during transport but there will be no increase in histamine unless the temperature rises above 4 °C for several hours. Once with the customer, product will be stored near zero.

Assumption 1: Histamine-decarboxylase activity leads to a ten-fold increase in histamine during processing, air freight and marketing.

Inputs to Risk Ranger for post-process storage and handling

Question 9: Effectiveness of post-processing ten-fold increase in hazard

Assess potential for product to reach toxic level

At this stage you must decide how much the growth of histamine-producers will cause fish to become toxic to consumers.

In the United Kingdom, levels of histamine >10 mg/100g fish are considered to be potentially toxic (Scoging, 1998) while in Australia the Food Standards Code has set 20 mg/100 g as the upper limit in any sample. The United States FDA set a level of concern at 10 mg/100 g.

Fletcher *et al.* (1998) showed that histamine-producers generally must reach a level $>10^7/cm^2$ to cause levels of histamine >5 mg/100 g so, for the present assessment, an assumption was made that a level of $10^8/cm^2$ was needed for fish to be toxic.

A summary of exposure assessment data is presented in Table 34, together with the amount of growth required in the processing, air freight and marketing sectors for histamine to reach levels ($10^8/cm^2$) that are associated with HFP.

TABLE 34

Increase in histamine-producing bacteria during processing air freight and marketing

Risk Ranger		Level on first caught fish	Total histamine producers
Question 6	Initial bacterial level on fish	$10/cm^2$	$10/cm^2$
Question 7	Increase on board	1 000x	$10\ 000/cm^2$
Question 9	Post-process increase	10x	$100\ 000/cm^2$
Question 10	Increase needed to toxic level	1 000x	$100\ 000\ 000/cm^2$

Inputs to Risk Ranger for increase to intoxication level

Question 10: Increase to intoxication: 1 000-fold increase in histamine producers

Determine effect of meal preparation on toxin levels

Histamine is heat-stable and so the method of preparation in the home or restaurant has no effect on the level of toxicity in the fish.

Inputs to Risk Ranger for effect of meal preparation

Question 10: Effect of meal preparation: Preparation has no effect on the hazard

5.4.5 Risk characterization

In this section you use information obtained from the hazard characterization and exposure assessment for input into Risk Ranger to examine the effect of temperature control aboard the vessel on the risk of getting HFP. The estimate of risk will be a risk ranking.

Inputs for fish caught from small boats are inserted into Table 35. This is a record of the risk assessment that allows reviewers to see exactly how the final estimate was obtained.

TABLE 35
Semi-quantitative risk characterization of HFP of fish from small boats

Risk criteria	Inputs to Risk Ranger
Dose and severity	
Hazard severity	Mild – sometimes requires medical attention
Susceptibility	General – all population
Probability of exposure	
Frequency of consumption	Monthly
Proportion consuming	Few (5%)
Size of population	270 million
Probability of contamination	
Probability of raw product contaminated	1%
Effect of processing	No change in prevalence, but there is 1 000x increase in histamine producing bacteria
Possibility of recontamination	10%
Post-process control	Allows 10-fold increase in hazard
Increase to infective dose	1 000 times
Meal preparation	Not effective in reducing hazard
Predicted annual illnesses	40 000
Risk ranking (0–100)	41

5.4.6 Risk estimate

The risk ranking is 41 with estimated annual illness of 40 000 from total servings numbering around 40 million.

5.4.7 Identification of critical data gaps

In making this assessment several assumptions were made:

Assumption 1: That all (100 percent) tuna landed contain histamine-producing bacteria in the gills and gut, and on the skin (see Kim *et al.*, 2001).

Assumption 2: That these bacteria are present at 10/cm² of gill surface or 10/g of gut contents (see Kim *et al.*, 2001).

Assumption 3: That the contamination is confined to fish surfaces, and the deep muscle tissues remain sterile.

Assumption 4: That a 30 kg tuna will give around 250 servings of 100 g of which 1 percent (servings with external tissues on which histamine has been produced) will be contaminated with sufficient histamine to cause illness.

Assumption 5: That, in fish held at 25–28 °C, histamine-producers have a doubling time of 60 minutes without any delay due to lag phase (typical doubling time for mesophilic *Enterobacteriaceae*).

Assumption 5: That during processing, there is a recontamination rate of 10 percent because the numbers of histamine-producers have multiplied and will be transferred to other areas of the fish.

Assumption 6: Histamine-decarboxylase activity leads to a tenfold increase in histamine during processing, air freight and marketing

5.4.8 Risk management and communication issues

Risk management is made difficult because of the need to accommodate a number of competing interests. The following scenario is typical of how risk managers, communicators and assessors must cooperate to achieve the best and safest outcomes.

The risk managers consider all boats should ice fish immediately after landing aboard the vessel so that the sites of microbiological concern are reduced to a temperature that will control histamine-producing bacteria.

Public comment

The decision to make icing of fish mandatory is communicated to several hundred operators. The operators respond that:

- *At least 100 kg of ice would be needed for each boat for each trip – a total of 30 tonnes for the entire fleet – a need that is impossible to service because the ice plant does not have the capacity.*
- *There is an added cost for the purchase of ice.*
- *There are safety concerns about having the extra load aboard the boat.*
- *There is no room aboard the vessels for an ice chest.*
- *Product from small boats has never killed anyone or made them ill.*

During election years several thousand votes come from the small fisheries sector.

The Minister of Fisheries asks the risk managers to reconsider all aspects of the situation:

- *Public health concerns in the consumer country.*
- *Potential loss of an export market if there is a problem in the consumer country.*
- *Loss of several hundred incomes if the fishery is closed down.*
- *Inability to supply sufficient ice.*
- *On-board safety concerns.*
- *Possible legal action by the small boat cooperative.*

Risk management decisions

The risk managers decide:

- *An ice-plant can be built and ice made available at reasonable (subsidized) cost.*
- *Boats can be modified so that the seats become insulated containers. Other spaces can also be modified so that the boats are capable of carrying up to 100 kg of ice.*

It is stated that typical catches are 50–80 kg/trip but that, sometimes, up to 200 kg is caught. Fishers wish to take only 50 kg of ice for each trip for reasons of space and cost. This will result in only partial icing.

Further risk assessment work

You are required to study the effect of partial icing on histamine formation.

Specifically, if fish are gilled and gutted immediately on landing aboard the vessel and the temperature of the sites of microbiological concern is reduced, how will this affect predicted histamine levels.

This is a data-logging/predictive microbiology exercise, for which you are allowed one month.

Risk assessment of partial icing of fish from small boats

By inserting data loggers just below the skin of the gut cavity of fish (a site of microbiological concern) the temperature:time parameters over the trip are determined. Figure 3 shows temperature profiles for fish caught early in the fishing trip.

From Figure 5 it can be seen that, on early-caught fish, the sites of microbiological concern are quickly brought below 5 °C. However, as more fish are caught and ice slowly melts, product temperatures gradually rise to around 10 °C. Chilling in ice imposes a lag phase on mesophilic histamine-producing bacteria which, together with very slow growth rates at 5–10 °C, will prevent growth of histamine-producers for the duration of the fishing trip. The result will be little production of histamine decarboxylase. Once on land, fish are actively chilled in ice slurry and product surfaces are quickly returned to zero.

From Table 36 it can be seen that many of the inputs to Risk Ranger remain the same as for the initial risk assessment. The initial prevalence of contamination remains at 1 percent; recontamination during processing is 10 percent. The critical difference is

Small alias with an icebox ready to locate within the cabin. Space is limited but the catch can now be cooled immediately on landing aboard the vessel

FIGURE 5
Fish temperatures (°C) for partially iced fish

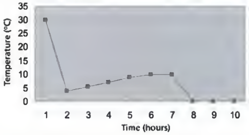


TABLE 36
Semi-quantitative risk characterization of HFP of partially-iced fish

Risk criteria	Inputs to Risk Ranger
Dose and severity	
Hazard severity	Mild – sometimes requires medical attention
Susceptibility	General – all population
Probability of exposure	
Frequency of consumption	Monthly
Proportion consuming	Few (5%)
Size of population	270 million
Probability of contamination	
Probability of raw product contaminated	1%
Effect of processing	No effect on prevalence or on population of histamine producing bacteria
Possibility of recontamination	10%
Post-process control	None
Increase to infective dose	10 000 000 times
Meal preparation	Not effective in reducing hazard
Predicted annual illnesses	4 cases per decade
Risk ranking (0–100)*	12

* Note that a change in risk ranking by an increment of "six" is equivalent to a tenfold change in risk

the effect of partial icing on preventing increase in histamine-producing bacteria on fish during storage on the boat. This has two important effects on inputs to Risk Ranger for Questions 9 and 10.

For Question 10, since there is no production of histidine decarboxylase on the boat, there is no enzymatic production of histamine during processing, air freight and marketing.

For Question 11, the level of histamine-producers linked with illness remains at $10^8/cm^2$ or /g. But, because of temperature control on the boat, the level of histamine producers is contained around 10 cm^2 or /g making the increment needed to cause illness $10^7/cm^2$ or /g.

Risk estimate

The risk ranking is 12, compared with 41 for un-iced fish. The reduction in ranking (29) is equivalent to a reduction

in risk of almost 100 000. Estimate of illness is four every decade, compared with 40 000/annum for fish held on the boat at ambient temperature.

5.5 PATHOGENIC *VIBRIO PARAHAEMOLYTICUS* IN OYSTERS EATEN RAW: QUANTITATIVE RISK ASSESSMENT

The situation

Your country has a flourishing oyster industry and supplies your own domestic market and several export markets. Following outbreaks of food poisoning in the United States caused by Vibrio parahaemolyticus, *and a QRA by that country, your government decides to undertake its own risk assessment.*

Your task is to assemble a team to do this process and you are given six months to complete a QRA.

5.5.1 Purpose of the assessment

The purpose of the assessment is to estimate the risk of disease caused by *V. parahaemolyticus* in oysters grown in your country to two populations:

- your domestic population of five million;
- populations in countries which import your oysters (combined populations of 300 million).

The risk estimate will be annual predicted illnesses from *V. parahaemolyticus* in oysters.

5.5.2 Your approach to the QRA

Team selection

You select a team which comprises:

- the technical director of the Oyster Association, who will supply data on production, consumption, export data and research information;
- a shellfish microbiologist who has specialist knowledge on vibrios;
- a modeller who has experience with risk assessments;
- a food technologist who has knowledge of how oysters are processed and packaged;
- an epidemiologist who will research vibrio-induced illness in your country.

You will coordinate this team and prepare the risk assessment report.

Strategy

Your team is aware that a QRA already exists and believes that it is important to use the same modelling approach but to modify it in two ways:

- make the model reflect the growing, harvesting and processing practices in your country;
- include data specific for your country.

Your team believes this approach will satisfy importing country requirements and, at the same time, reflect the situation in your industry.

Assessing data gaps

Your team assesses the data available to the QRA and finds a number of relevant studies on total *V. parahaemolyticus* levels according to season. There are two data gaps that must be filled as soon as possible:

- levels of pathogenic strains of *V. parahaemolyticus* in oysters at the time of sale;
- consumption patterns, especially the percentage eaten raw or lightly cooked.

Work programme

A study is begun to isolate pathogenic strains using gene probe technology. This will take three months. The oyster industry will also survey consumption patterns, again with a three-month deadline. You initiate a series of meetings to set up the farm-to-fork model and your modeller examines the United States model in detail because it will form the basis for your assessment.

5.5.3 Hazard identification

There are a number of sources that summarize the evidence establishing *Vibrio parahaemolyticus* as a hazard in seafood consumption, for example, the United States FDA risk assessment (FDA, 2001b) and an appraisal: *Opinion of the Scientific Committee on Veterinary Measures relating to Public Health on* Vibrio vulnificus *and* Vibrio parahaemolyticus *in raw and undercooked seafood* issued by the European Commission. Both reports are included in the Resources Bank.

In summary, it is a marine micro-organism occurring in estuarine waters throughout the world, first identified as a food-borne pathogen in Japan in the 1950s (Fujino *et al.*, 1953). By the late 1960s and early 1970s, *V. parahaemolyticus* was recognized as a cause of diarrhoeal disease worldwide, although most common in Asia and the United States. Vibrios concentrate in the gut of filter-feeding molluscan shellfish such as oysters, clams, and mussels where they multiply. Although thorough cooking destroys these organisms, oysters are often eaten raw and, at least in the United States, are the most common food associated with *Vibrio* infection (Hlady, 1997).

In Asia, *V. parahaemolyticus* is a common cause of food-borne disease. In general the outbreaks are small in scale, involving fewer than ten cases, although they occur frequently. Prior to 1994, the incidence of *V. parahaemolyticus* infections in Japan had been declining, however, in 1994–95 there were 1 280 reports of infection due to the organism (IDSC, 1999) and during this period, *V. parahaemolyticus* food poisonings outnumbered those of *Salmonella* food poisoning. For both years, the majority of the cases occurred in the summer, with the largest number appearing in August.

Between 1986 and 1995, 197 outbreaks of food-borne disease were caused by *V. parahaemolyticus* in Taiwan (Pan *et al.*, 1997) while in 1997 over 200 outbreaks were reported, including an outbreak of 146 cases acquired from boxed lunches (ISID, 1999).

During 1997 and 1998 there were more than 700 cases of illness due to *V. parahaemolyticus* in the United States, the majority of which were associated with the consumption of raw oysters. In two of the 1998 outbreaks a serotype of *V. parahaemolyticus*, O3:K6, previously reported only in Asia, emerged as a principal cause of illness for the first time. Subsequent studies on these strains have revealed their pandemic spread.

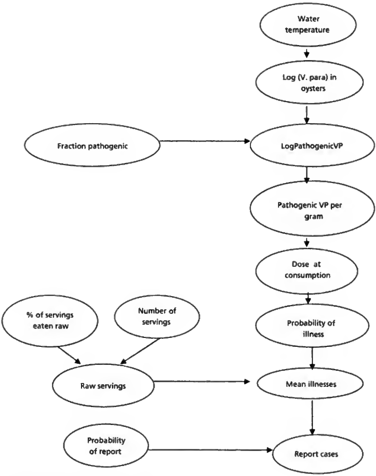
In Europe few data exist on the incidence of *V. parahaemolyticus* infections, one of the reasons being that such infections are not notifiable.

5.5.4 Exposure assessment

Stage 1: Modelling the process

The purpose is to quantify the exposure of consumers to pathogenic *V. parahaemolyticus* from the consumption of raw oysters. Often this is done using a model that incorporates all phases in the harvest – post-harvest – consumption continuum to identify steps that contribute most to risk, so that effective risk reduction strategies can be designed. The first stage is for the modeller on your team to construct a conceptual model linking all important stages for which information is required. Such a model is presented below, and it can be constructed in risk assessment software so that data can be included directly.

The model sets out the data you need to obtain in order to do the assessment and links them, showing how they influence other factors. The model also sets your work program over the next three months, in order to gather the data for the modeller.



Stage 2: Obtaining water temperature data

It is well known that appearance of *V. parahaemolyticus* in natural waters is linked with water temperature, so you need to find at least one year of temperature recordings at your major oyster growing areas. This presents no problem because all shellfish farmers measure temperatures and salinities as part of their management system. You are able to obtain a full year's data (Table 37) from which it should be noted that, as a southern hemisphere country, your summer is December–April.

Stage 3: Linking water temperature with numbers of V. parahaemolyticus

There have been several studies in which the researchers measured water temperatures and populations of *V. parahaemolyticus* in oysters (Table 38).

This analysis is extremely important for your risk assessment because it establishes the link between water temperature and populations of *V. parahaemolyticus* in

oysters. It is especially important for your assessment because of your time constraints. Your modeller will tell you the above data "anchor" the whole risk assessment. This means that the data provide a point of reference that can be used to compare risks as higher or lower without knowing the actual size of the risk. This is useful in international trade negotiations, which are based on the idea of "equivalence".

TABLE 37

Water temperature recordings (°C) at a major oyster growing area

	Minimum	Mean	Maximum
Jan	19	23	26
Feb	19	24	27
Mar	20	23	25
April	19	20	22
May	17	19	21
June	15	18	20
July	14	17	19
Aug	13	15	18
Sept	13	15	17
Oct	15	17	18
Nov	16	18	20
Dec	18	20	23

Stage 4: Measuring levels of V. parahaemolyticus *in oysters*

Ideally, you need to know how many *V. parahaemolyticus* are in market-ready oysters over an annual cycle. You do not have time for a whole cycle but, fortunately, you can sample at the warmest months, when the *V. parahaemolyticus* concentration in oysters will be highest. You also need to know how many of the organisms are pathogenic.

TABLE 38

Summary of water temperature and *V. parahaemolyticus* in oysters

Water temperature (°C)	*V. parahaemolyticus*/g oysters
<15	Not detected
15–20	<10
20–25	10–100
>25	100–1000

You are able to purchase gene probes, which can highlight *V. parahaemolyticus* colonies on culture plates and can also distinguish pathogenic types. So you have a straightforward method of gathering information, and it is just a question of obtaining samples for the laboratory to do the testing.

This laboratory phase of the work is done during the warmest months and produces the following data on total *V. parahaemolyticus* and on pathogenic strains (Table 39).

Stage 5: Gathering consumption data

While the scientists are doing the laboratory work your industry experts gather data on consumption patterns in the country to which you are exporting. Remember, this country is your customer and you are aiming the risk assessment at their situation.

It is not difficult to get export statistics that tell you the tonnage exported, from which you can calculate the number of oysters eaten. You know the population of the country but obviously not everyone eats your oysters so you need to find out the proportion that does. This is impossible to define except in broad terms, but your marketing agents are able to tell you a great deal of useful information. In summary, you are able to confirm that each year:

- Your oysters are sold in around ten major cities and are eaten either in markets or restaurants.
- Most people buy six oysters, to give a serving size of 100 g; 12 oysters is the next popular serving size (200 g).
- More than 95 percent are eaten raw or lightly cooked.

You are able to calculate that you export the equivalent of 10 million servings of six oysters (100 g).

TABLE 39

Total and pathogenic *V. parahaemolyticus* in oyster meat

	Total *V. parahaemolyticus*		Pathogenic *V. parahaemolyticus*	
	Prevalence	Mean log/g (antilog)	Prevalence	Mean log/g (antilog)
Jan	45/50	1.5 (31)	10/50	0.8 (6)
Feb	50/50	2.2 (160)	15/50	1.2 (16)
Mar	50/50	25 (315)	15/50	1.8 (63)

Stage 6: Preparing the data for modelling

You now have the exposure data needed to give to the modeller. It is important to assemble the team to go over the data and make the modeller familiar with the data; they are not just numbers – the modeller must fully understand the data and what they mean.

Modellers are interested in the quality of the data, specifically the variability and uncertainty. They need to measure these properties and incorporate them into the calculations of a risk assessment. Modellers handle variability and uncertainty in the data in a similar way – by making a series of distributions for the important parameters of the model. One commonly used distribution is called Triangular (or 'triang') and involves describing the range of possible values by the minimum, maximum and most likely value.

Your modeller tells you that data in Table 37 (Monthly water temperatures) are already set out as a distribution (max, min and mean, or most likely) for each month.

In Table 38 (Population of *V. parahaemolyticus* as affected by water temperature), bacterial numbers are described as the most likely range. Your modeller modifies these data by making a triang of the most likely range and a triang of the variability (Standard Deviation).

In Table 39 (Mean numbers of pathogenic *V. parahaemolyticus*), the modeller again makes triangular distributions (min, max, most likely) of the monthly means.

After examining the consumption data, your modeller tells you there is great variability. Apparently the most popular serving is 6 (approx. 100 g), followed by 12 oysters. But a proportion of the population eats 24 oysters at one sitting and some people may eat up to 60 at one time. At the other end of the scale, some consumers only eat one oyster. Again this variability can be modelled with a triangular distribution using min = 20 g, mean = 100 g and max = 500 g.

The data are processed through special software by the modeller so they are ready for analysis using risk assessment software.

5.5.5 Dose-response

The dose-response developed in the United States study is shown below.

The dose-response curve is based on four feeding trials of volunteers and, because of the small number of people used during these studies, there is considerable uncertainty about the best estimate of the dose-response. Almost all volunteers became ill when they were fed between 1 million and 1 billion *V. parahaemolyticus* but there are no points on the upward part of the curve. This is going to lead to great uncertainty and your modeller notes that the United States modellers use several statistical methods for characterizing the uncertainty of the dose-response parameters, including likelihood ratio-based confidence regions and bootstrapping techniques (parametric or non-parametric).

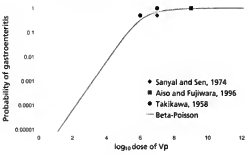
As well as uncertainty, the modeller reminds you that a number of assumptions have been made, including that:

- The way healthy volunteers respond to oral challenge is typical of the general population.
- The virulence of the pathogens or susceptibility of the host does not vary.
- The Beta-Poisson dose-response model is reasonable for use in characterizing risk of illness when consuming *Vibrio* spp.

5.5.6 Risk characterization

Your modeller now puts all the data and distributions into a software package designed to calculate the risk estimates and runs a large number of simulations (iterations). The risk assessment software samples all possible combinations of distributions, although it samples the more likely values more frequently than those at the maximum and

FIGURE 6
An example of a dose-response curve



minimum. Your modeller now works with the outputs to produce a risk estimate of number of cases per year in the importing country.

The outputs are summarized in Figure 7, which describes the relationship between the probabilities of illness per serving with the probability that the estimate is correct. For example, the graph peaks at a 50 percent probability that 1 in 100 000 serves will cause illness. If all the probabilities under the graph are added, the most likely result is that one meal in 1 million serves will cause illness.

Since there are 10 million servings exported, the most likely result is that they will cause 10 illnesses. The assessment also predicts the range of illnesses will be 1–800/annum. From the results the modeller can state, with 95 percent confidence, that there will be fewer than 316 illnesses from 10 million of your oysters.

Reality check

The results of the assessment, with its prediction of illnesses, make you examine the situation at home, where around 30 million servings are consumed. According to the assessment, there should be 30 cases each year. The epidemiologist on the team examines health records for the past decade and finds that there have been no recorded illnesses from consumption of *V. parahaemolyticus* in oysters. This evidence tells you with certainty that there have been no outbreaks, because they would have been reported. However, there may well have been sporadic cases of mild gastroenteritis, where consumers did not visit their doctor because the symptoms did not warrant it. You conclude that the risk estimate is not greatly removed from reality.

Uncertainty and variability

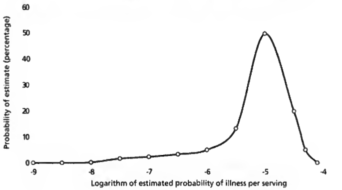
There is considerable uncertainty surrounding the dose response because only a small number of subjects were involved in the trials and they were not very representative of the whole population. Because you have not followed an annual cycle of pathogen numbers in oysters there is variability in the dose consumed.

Sensitivity analysis

You modeller is able to say that the only strong correlation with risk is water temperature and that the analysis indicates almost all cases were predicted for the warmer months (December–April).

FIGURE 7

Probability of illness per serving versus probability that the estimate is correct



Reporting the results

You report to your customer (the importing country). The risk estimate (ten cases per annum) is seen against the predictions from their own assessment of more than 2 000 cases per annum. There are discussions between your countries' governments on mitigation strategies. Your government proposes not exporting chilled product during the warmest months. It is an offer to reduce the risk to the importing country because you will retain the highest risk product at home. After consultation, the importing country government decides the risk associated with importing your product is an acceptable one.

The risk assessment has uncertainties and variabilities, but it has served its purpose by providing your customer with information on which to make an informed decision.

References

Ababouch, L., Afilal, M.E., Benabdeljelil, H. & Busta, F.F. 1991. Quantitative changes in bacteria, amino acids and biogenic amines in sardine (*Sardina pilchardus*) stored at ambient temperature (25–28 °C) and in ice. *International Journal of Food Science and Technology*, 26: 297–306.

Aiso, K. & Fujiwara, K. 1996. Feeding tests of the pathogenic halophilic bacteria. Annual Research Report Institute of Food Microbiology Chiba University, 15: 34–38.

Arcilaherrera, H., Castellonavarrete, A., Mendozaayora, J., Monterocervantes, J., Gonzalezfranco, M.F. & Britovillanueva, W.O. 1998. Ten cases of ciguatera fish poisoning in Yucatan. *Revista de Investigacion Clinica*, 50: 149–152.

Bryan, F. 1979. Epidemiology of food-borne diseases. *In* H. Riemann & F. Bryan, eds. *Food-borne infections and intoxications.* New York, USA, Academic Press.

Cassin, M.H., Lammerding, A.M., Todd, E.C.D., Ross, W. & McColl, R.S. 1998. Quantitative risk assessment for Escherichia coli O157:H7 in ground beef hamburgers. *International Journal of Food Microbiology*, 41: 21–44.

Clifford, M.N. & Walker, R. 1992. The aetiology of scombrotoxicosis. *International Journal of Food Science and Technology*, 27: 725–726.

Conaty, S., Bird, P., Bell, G., Kraa, E., Grohmann, G. & McAnulty, J. 2000. Hepatitis A in New South Wales, Australia from consumption of oysters: the first reported outbreak. *Epidemiology and Infection*, 124: 121–130.

Corlett, D.A. & Pierson, M.D. 1992. Hazard analysis and assignment of risk categories. *In* M.D. Pierson & D.A. Corlett, Jr, eds. *HACCP: principles and applications*, pp. 29–38. New York, USA, Van Nostrand Reinhold.

Coultate, T.P. 1992. *Food: the chemistry of its components.* Royal Society of Chemistry, Cambridge, UK.

D'Aoust, J-Y. 1994. *Salmonella* and the international food trade. *International Journal of Food Microbiology*, 24: 11–31.

Davidson, P.W., Myers G.J., Cox, C. Axtell, C., Shamlaye, C., Sloane-Reeves, J., Cernichiari, E., Needham, L., Choi, A., Wang, Y., Berlin, M. & Clarkson, T.W. 1998. Effects of prenatal and postnatal MeHg exposure from fish consumption on neurodevelopment. *Journal of the American Medical Association*, 280: 701–707.

European Union (1991 and 1995). Council Directive 91/493/EEC and 1995 amendment laying down health conditions for the production and placing on the market of fishery products. *Official Journal of the European Commission*, L268: 15–32.

FAO. 2004. *Assessment and management of seafood safety and other quality aspects*, by L. Ababouch & L. Gram. FAO Fisheries Technical Paper 444. Rome.

FAO/NACA/WHO. 1999. Food safety issues associated with products from aquaculture: report of a joint FAO/NACA/WHO study group. *WHO technical report series*: 883. Joint FAO/NACA/WHO Study Group on Food Safety Issues Associated with Products from Aquaculture (1997: Bangkok, Thailand).

FAO/WHO. 2001. *Codex Alimentarius food hygiene basic texts.* 2nd edition. Rome.

FAO/WHO. 2002. *Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts.* Report of a Joint FAO/WHO Consultation, Kiel, Germany. Rome.

FDA (United States Food and Drug Administration). 1994. Mercury in fish: cause for concern? *FDA Consumer Magazine*, 28(7).

FDA. 1999. *Bad bug book (foodborne pathogenic microorganisms and natural toxins).* Washington, DC.

FDA. 2001a. *Fish and fishery products hazards and controls guide.* 3rd edition. Washington, DC, Office of Seafood. 326 pp.

FDA. 2001b. *Draft risk assessment on the public health impact of* Vibrio parahaemolytius *in raw molluscan shellfish.* Centre for Food Safety and Applied Nutrition, US FDA, Washington, DC.

Fletcher, G.C. 1995. Histamine and histidine in New Zealand marine fish and shellfish species, particularly kahawai *(Arripis trutta). Journal of Aquatic Food Production Technology*, 4: 53–74.

Fletcher, G.C., Summers, G. & van Veghel, P.W.C. 1998. Levels of histamine and histamine-producing bacteria in smoked fish from New Zealand markets. *Journal of Food Protection*, 61(8): 1064–1070.

Fujino, T., Okuno, Y., Nakada, D., Aoyoma, A., Fukai, K., Mukai, T. & Ueho, T. 1953. On the bacteriological examination of shirasu food poisoning. *Med. J. Osaka Univ,.* 4: 299–304.

Glaziou, P. & Martin, P.M.V. 1993. Study of factors that influence the clinical response to Ciguatera fish poisoning. *Toxicon*, 31: 1151–1154.

Grohmann, G. 1997. Viruses, food and environment in food-borne microorganisms of public health significance. *In* A.D. Hocking, G. Arnold, I. Jenson, K. Newton & P. Sutherland, eds. *Food-borne microorganisms of public health significance*. Australian Institute of Food Science and Technology Inc., NSW Branch Food Microbiology Group, North Sydney, Australia.

Habermehl, G.G., Krebs, H.C., Rasoanaivo, P. & Ramialiharisoa, A. 1994. Severe ciguatera poisoning in Madagascar: A case report. *Toxicon*, 32 (12): 1539–1542.

Hlady, W.G. 1997. *Vibrio* infections associated with raw oyster consumption in Florida, 1981–1994. *Journal of Food Protection*, 60: 353–357.

Huss, H.H., Reilly, A. & Ben Embarek, P.K. 2000. Prevention and control of hazards in seafoods. *Food Control,* 11: 149–156.

IDSC (International Disease Surveillance Center). 1999. *Vibrio parahaemolyticus*, Japan 1996–1998, IASR Infectious Agents Surveillance Report, 20 (7): 1–2.

ISID (International Society for Infectious Diseases. 1999. *Vibrio parahaemolyticus*, Taiwan: Background. PROMED-digest, 28 May 1999.

Johnson, B.L. 1998. Testimony of Barry L. Johnson, Ph.D., Assistant Surgeon General Assistant Administrator, Agency for Toxic Substances and Disease Registry Public Health Service, US Department of Health and Human Services Before the Subcommittee on Clean Air, Wetlands, Private Property, and Nuclear Safety Committee on Environment and Public Works United States Senate, 1 October 1998. Accessed on 2 September 1999 from http://www.senate.gov/~epw/105th/joh_10-1.htm.

Katz, A. R., Terrellperica, S. & Sasaki, D.M. 1993. Ciguatera on Kauai – investigation of factors associated with severity of illness. *American Journal of Tropical Medicine & Hygiene*, 49: 448–454.

Kim, S-H., Field, K.G., Chang, D-S., Wei, C-I. & An, H. 2001. Identification of bacteria crucial to histamine accumulation in Pacific mackerel during storage. *Journal of Food Protection*, 64(10): 1556–1564.

Kjellstrom, T.P., Kennedy, P., Wallis, S. & Mantell, C. 1989a. Physical and mental development of children with prenatal exposure to mercury from fish. Stage 1: preliminary tests at age 4. National Swedish Environmental Protection Board Report 3080. Solna, Sweden.

Kjellstrom, T.P., Kennedy, P., Wallis, S., Stewart, A., Friberg, L., Lind, B., Wutherspoon, T. & Mantell, C. 1989b. Physical and mental development of children with prenatal exposure to mercury from fish. Stage 2: interviews and psychological tests at age 6. National Swedish Environmental Protection Board Report 3642. Solna, Sweden.

Klausen, N.K. & Huss, H.H. 1987. Growth and histamine production by *Morganella morganii* under various temperature conditions. *International Journal of Food Microbiology*, 5: 147–156.

Lees, D. 2000. Viruses and bivalve shellfish. *International Journal of Food Microbiology*, 59: 81–116.

Lehane, L. 1999. *Ciguatera fish poisoning. A review in a risk-assessment framework.* National Office of Animal and Plant Health, Agriculture, Fisheries and Forestry Australia.

Lehane, L. & Lewis, R.J. 2000. Ciguatera: the risk remains. *International Journal of Food Microbiology*, 61: 91–125.

Lehane, L. & Olley, J. 1999. *Histamine (scombroid) fish poisoning: a review in a risk-assessment framework*. National Office of Animal and Plant Health, Canberra.

Lehane, L. & Olley, J. 2000. Histamine fish poisoning revisited. *International Journal of Systematic Microbiology*, 58: 1–37.

Levin, L. 1998. Statement of Leonard Levin, Ph.D. EPRI Palo Alto, California to US Senate Subcommittee on Clear Air, Wetlands, Private Property, and Nuclear Safety Committee on Environment and Public Works, Washington, DC. 1 October 1998. Accessed 2 September 1999 from http://www.senate.gov/~epw/105th/lev_10-1.htm.

Lindqvist, R. & Westöö, A. 2000. Quantitative risk assessment for *Listeria monocytogenes* in smoked or gravad salmon and rainbow trout in Sweden. *International Journal of Food Microbiology*, 58: 181–196.

Linnan, M.J., Mascola, L., Lou, X.D., Goulet, V., May, S., Salimen, C., Hird, D.W., Yonekura, M.L., Hayes, P., Weaver, R. *et al.* 1988. Epidemic listeriosis associated with Mexican-style cheese. *The New England Journal of Medicine*, 319(13): 823–828.

Mahaffey, K. 1998. MeHg exposure and neurotoxicity (Editorial). *Journal of the American Medical Association*, 280(8): 737–738.

Mascola, L., Tormey, M., Dassey, D., Kilman, L., Harvey, S., Medina, A., Tilzer, A. & Waterman, S. 1996. *Vibrio vulnificus* infections associated with eating raw oysters – Los Angeles, 1996. *Morbidity and Mortality Weekly Reports*, 45(29): 621–624.

McAnulty, J. 1990. *Vibrio* warning. *NSW Public Health Bulletin*, 1: 12.

Mead, P.S., Slutsker, L., Dietz, V. *et al.* 1999. Food-related illness and death in the United States. *Emerging Infectious Diseases*, 5: 607–625.

Morinaga, S., Kawasaki, A. Hirata, A.H. Suzuki, S. & Mizushima, Y. 1997. Histamine poisoning after ingestion of spoiled raw tuna in a patient taking isoniazid. *Internal Medicine*, 36(3): 198–200.

Myers, G. 1998. Statement by the University of Rochester Research Team Studying the Effects of MeHg Read Before the Senate Subcommittee on Clean Air, Wetlands, Private Property and Nuclear Safety, Committee on Environment and Public Works, 1 October 1998 (available at http://www.senate.gov/~epw/105th/mye_10-1.htm).

National Academy of Sciences. 2000. *Toxicological effects of mercury*. The National Academy of Sciences, USA.

Pan, T.M., Chai, T.-J.,Lee, C.L., Chien, S.W. & Horng, C.B. 1997. Foodborne disease outbreaks due to bacteria in Taiwan, 1986 to 1995. *Journal of Clinical Microbiology*, 35: 1260–1262.

Poli, M. A., Lewis, R.J., Dickey, R.W., Musser, S.M., Buckner, C.A. & Carpenter, L.G. 1997. Identification of Caribbean ciguatoxins as the cause of an outbreak of fish poisoning among US soldiers in Haiti. *Toxicon*, 35: 733–741.

Quod, J.P. & Turquet, J. 1996. Ciguatera in Reunion Island (SW Indian Ocean): Epidemiology and clinical patterns. *Toxicon*, 37(1): 779–785.

Richardson, G.M. 1995. *Assessment of mercury exposure and risks from dental amalgam.* Medical Devices Bureau, Environmental Health Directorate, Health Canada.

Rogers, P. & Staruszkiewicz, W. 1997. Gas chromatographic method for putrescine and cadaverine in canned tuna and mahimahi and fluorometric methods for histamine (minor

modification of AOAC Official Method 977.13): *Collaborative study. Journal of AOAC International*, 80(3): 591–602.

Rose, J. B. & Sobsey, M.D. 1993. Quantitative risk assessment for viral contamination of shellfish and coastal waters. *Journal of Food Protection*, 56: 1043–1050.

Ross, T. & Sumner, J. 2002. A simple, spreadsheet-based, food safety risk assessment tool. *International Journal of Food Microbiology*, 77: 39–53.

Ruff, T.A. & Lewis, R.J. 1994. Clinical aspects of ciguatera: An overview. *Memoirs of the Queensland Museum*, 34: 609–619.

Sanyal, S.C. & Sen, P.C. 1974. Human volunteer study on the pathogenicity of *Vibrio parahaemolyticus*, p. 227-230. *In* T. Fujino, G. Sakaguchi, R. Sakazaki & Y. Takeda, eds. International Symposium on *Vibrio parahaemolyticus*. Tokyo, Saikon Publishing Company.

Scoging, A. 1998. Scombrotoxic (histamine) fish poisoning in the United Kingdom: 1987 to 1996. *Communicable Disease and Public Health*, 1: 204–205.

Shalaby, A.R. 1996. Significance of biogenic amines to food safety and human health. *Food Research International*, 29(7): 675–690.

Simidu, W. & Hibiki, S. 1955. Studies on putrefaction of aquatic products. 23. On the critical concentration of poisoning for histamine. *Bulletin of the Japanese Society of Scientific Fisheries*, 21:365 (cited by Taylor, 1986).

Smith de Waal, C., Alderton, L. & Jacobsen, M.F. 2000. *Closing the gaps in our federal food-safety net*. Center for Science in the Public Interest, Washington, DC.

Sours, H.E. & Smith, D.G. 1980. Outbreaks of foodborne disease in the United States, 1972-78. *Journal of Infectious Diseases*, 142: 122–125.

Sumner, J. & Ross, T. 2002. A semi-quantitative seafood safety risk assessment. *International Journal of Food Microbiology*, 77: 55–59.

Takikawa, I. 1958. Studies on pathogenic halophilic bacteria. *Yokohama Medical Bulletin*, 9: 313–322.

Taylor, S.L. 1986. Histamine food poisoning: Toxicology and clinical aspects. *Critical Reviews in Toxicology*, 17(2): 91–128.

Todd, E.C.D. 1995. Estimated costs of paralytic shellfish, diarrhetic shellfish and ciguatera poisoning in Canada, p. 831-834. *In* P. Lassus, P. Arzul, E. Erard, P. Gentien & C. Marcaillou, eds. *Harmful marine algal blooms*. Paris, Lavoiser Publishing.

WHO. 1995. Application of risk analysis to food standards issues. Report of the Joint FAO/WHO Expert Consultation, Geneva, Switzerland. 13–17 March 1995. Geneva.

In recent years, the concept of risk has become paramount in international food regulation, and industries are increasingly required to undertake product risk assessment, particularly in the export arena. This publication has been developed as a complete package on how to undertake risk assessment for use by seafood technologists, regulators and health professionals. It is designed in five parts to guide the user through the risk assessment process. This publication also includes a CD-ROM – the Resources Bank – that provides extensive additional information for the would-be risk assessor.

ISBN 92-5-104951-3 ISSN 0429-9345

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TC/M/Y4722E/2/02.05/1000